IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION AT CINCINNATI

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DURAMED PHARMACEUTICALS, INC., :

Plaintiff, :

vs. :

WYETH-AYERST LABORATORIES, INC., :

Defendant. : PAGES 1 - 275

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HIGHLY CONFIDENTIAL

Videotape Deposition of PAUL SIMON

Washington, D.C.

Friday, October 11, 2002

Reported by: Susan D. Ashe, RMR Job No. 148412

Friday, October 11, 2002

9:13 a.m.

Videotape Deposition of PAUL SIMON, held at the law offices of:

Arnold & Porter

555 Twelfth Street, N.W.

Washington, D.C.

Pursuant to notice, before Susan D. Ashe, Registered Merit Reporter, a Notary Public of the District of Columbia.

For Plaintiff and the Witness:

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(513) 381-2838

BY: R. JOSEPH PARKER, ESQ.

For Defendant:

Winston & Strawn

35 West Wacker Drive

Chicago, Illinois 60601

(312) 558-6600

BY: GORDON DOBIE, ESQ.

ALSO PRESENT: William Lobb

Robert Cherouny, Videographer

C O N T E N T S

P R O C E E D I N G S

(Defendant's Exhibit Number 1075 was marked for identification.)

VIDEOGRAPHER: This is Tape No. 1 of the videotape deposition of Paul Simon, taken by the defendants, in the matter of Duramed Pharmaceuticals, Inc., versus Wyeth-Ayerst Laboratories, in the United States District Court for the Southern District of Ohio, Western Division at Cincinnati. Case number is C-1-00-735.

This deposition is being held at the offices of Arnold & Porter, 555 Twelfth Street, Northwest, Washington, D.C., on today's date -- which is October 11, 2002; and the time is approximately 9:13 a.m.

And my name is Robert Cherouny, from the firm of Esquire Deposition Services. And I'm the certified legal video specialist.

And the court reporter is Susan Ashe, also in association with Esquire.

And will the counsel please introduce

themselves and who they represent.

MR. PARKER: Joseph Parker, from Taft, Stettinius & Hollister, counsel for plaintiff, Duramed.

MR. DOBIE: Gordon Dobie, for the defendant, Wyeth.

VIDEOGRAPHER: And will the court reporter please swear in the witness.

Whereupon --

PAUL SIMON,

the Witness, called for examination by the Defendant, was duly sworn by the notary public and testified as follows:

EXAMINATION BY COUNSEL FOR DEFENDANT

BY MR. DOBIE:

Q. Would you please state your full name for the record?

A. Paul O. Simon --

Q. Mr. Simon --

A. -- S-i-m-o-n.

Q. -- as you probably heard, I'll be asking you a series of questions here today.

Have you ever had your deposition taken before?

A. Never been through this before, no.

Q. Well, you're doing great so far.

Please respond verbally to all of my questions. The nod of the head obviously can be picked up by the videographer, but the court reporter can't get that down. So you need to respond verbally. Understood?

A. Okay.

Q. If you need to take a break at some point, let me know. We can do that.

A. Okay.

Q. And if any questions are unclear, please let me know. And I'll try to restate it to make the question clear. Otherwise, I'll assume that you understood my question.

A. Okay.

Q. Agreed?

Okay. Let me hand you what we've marked as Exhibit 1075, and would you identify what Exhibit 1075 is for the record.

A. This is my rebuttal report.

MR. DOBIE: And let me hand you -- why don't we mark this as 1076.

(Defendant's Exhibit Number 1076 was marked for identification.)

BY MR. DOBIE:

Q. What is 1076, exhibit?

A. This is my resume.

Q. Mr. Simon, what I'd like to do here today is ask you some questions about your rebuttal report, Exhibit 1075.

And before we get into that in a lot of detail, I'd like to visit with you about your background if I could.

A. Yes, sir.

Q. And let me ask you first, in terms of your experience as an expert witness: Have you ever been retained by anyone to serve as an expert witness in any case?

A. No.

Q. How did you come to be retained as an expert witness for Duramed in this case?

A. I got a phone call from Carolyn Courville, who got my name from someone else as someone who had considerable experience and was available to do this.

She called me on the phone. We had a discussion.

Q. Who did she say that she got your name from?

A. Ed Thwaite.

Q. And who is Mr. Thwaite?

A. Ed Thwaite is a -- is another consultant.

Q. And was Mr. Thwaite working with Duramed to your understanding? Or...

A. I don't believe so.

Q. And what did Ms. Courville tell you about the case in that initial phone call?

A. She just basically asked me if I was familiar with the actions that were taken with Duramed and Wyeth-Ayerst. At which point I said, "No, I was not terribly familiar."

She asked me to send her a resume so that she could look at it and then have further

discussions, which she did.

Q. When was that first conversation?

A. Oh, my gosh. I'm going to say July.

Q. All right. So --

A. I'm guessing.

Q. Well, look at your report -- because that's got a date on it, doesn't it? -- Exhibit 1075.

A. Of when she called me?

Q. Well, you got a date of your report, September 24, 2002.

A. Correct.

Q. When in relation to that did she call you?

A. I think it was in July.

Q. July? And at that point, did you have a report from Dr. Kolassa that she was asking you to respond to?

A. No.

Q. Did you meet with Ms. Courville?

A. Yes.

Q. Where did you meet with her?

A. In Houston, Texas.

Q. And tell me what you recall about that initial meeting.

A. Basically, it was -- she had provided me some materials that were relevant to the case.

She asked me -- and clarified for me that I was going to be doing a rebuttal.

At this point when I had met her, I had already seen Dr. Kolassa's report. I had made some notes, and I met with her.

She clarified what it was that I was, you know, being retained to do; and that was to look at it, provide honest opinions -- good or bad -- with regard to the report.

And that was basically it.

Q. So did you have notes and things? Had you written on Dr. Kolassa's report?

A. I had written on -- yes.

Q. And you said "good or bad." Was there anything good in Dr. Kolassa's report?

A. Yes.

Q. Things that you agreed with?

A. Yes.

Q. What did you agree with?

A. Specifically, I agreed with his premise that the sales force is the most important tool that a company has in marketing a pharmaceutical product.

Q. Anything else?

A. Not that comes to mind.

Q. And is it your experience, based upon years in the pharmaceutical arena, that the sales force is the most important thing in marketing a product?

A. Definitely.

Q. And what companies have you worked at where you've found that to be true?

A. Well, I've worked at Hoffmann-LaRoche and started in sales. So I guess you might even say that I had a bit of sales experience.

Moved into marketing position at Roche. Worked at Bristol Myers, where I believe the same was still true there.

At Teva Pharmaceuticals they have sayings that, you know, nothing happens until a sale is made; and that's pretty much, you know, the kind

of thing that's true in the pharmaceutical industry.

We have to -- there has to be a conduit between the manufacturer and the customer -- in this case, the individual who writes the prescription.

And the sales rep is the face of the company to the physician.

So I believe that that's true anytime that you're going to be doing detailing or selling branded pharmaceuticals to physicians.

Q. So this rule of thumb that nothing happens until somebody makes a sales call on a physician --

A. Well, I wouldn't call it a "rule of thumb"; and perhaps I shouldn't have even gone there.

The idea, though, is that I truly believe that the pharmaceutical representative -- when you're dealing with pharmaceuticals, the physician is the customer. And the pharmaceutical representative is the face of the company with the doctor.

That's the important issue.

Q. Anything else that you can think of in Dr. Kolassa's report that you agree with?

A. Not specifically.

Q. How many hours have you spent working and analyzing the facts in this case?

A. Maybe 200.

Q. And what are you being paid per hour for your time?

A. $250 per hour.

Q. Now, at the time that you prepared your report that we've marked as Exhibit 1075, had you reviewed documents from Duramed --

A. Um-hum. Yes.

Q. -- documents from Wyeth?

You had reviewed various documents and exhibits --

A. Yes.

Q. -- in connection with the case?

And are there additional documents that you looked at after you had prepared your report?

A. Not that I can remember.

Q. All right. You mentioned Hoffmann-LaRoche. Let's walk through your experience if we could.

First, on the educational side, you have a B.S. degree in Pharmacy from Ohio Northern?

A. Yes.

Q. And are you a registered licensed pharmacist in Ohio, Pennsylvania, and Florida?

A. I am a -- yes.

My license is inactive in Florida and in Pennsylvania. Right now I just keep my home license active; but I am licensed -- and I did take the boards in Florida, yes.

Q. And you graduated from Ohio Northern University in -- what? -- about 1974?

A. '74, yes.

Q. '74. And you went to Hoffmann-LaRoche, I see, in 1976. What did you do between the time that you graduated in '74 --

A. I worked in pharmacy.

Q. What pharmacy?

A. Oh, I worked in a couple of different

retail settings. I also did relief work in hospitals.

You also have to do an internship, something to the tune of a thousand hours, before you can even get your license. I did that in Bellefontaine, Ohio.

My pharmacy experience, retail pharmacy experience, was principally in Ohio and Florida.

Q. When did you have pharmacy experience in Florida, what years was that?

A. I think I moved there in '75.

Q. So until when?

A. Till the end of '76.

So for about a year and a half.

Q. Have you worked as a pharmacist at any time since 1976?

A. No, no.

Q. So the last time you would have filled a prescription is 1976?

A. Probably. I would say, most likely, yes.

I was in the service for a while, in

the army, and stationed at Fort Sam Houston, where I did some pharmacy work and ran their manufacturing line.

Q. When was that?

A. Somewhere around 1976.

Q. So I've got you at Hoffmann-LaRoche in Nutley, New Jersey -- according to your resume -- in 1976.

A. No, you don't.

I started at Hoffmann-LaRoche in 1976 as a sales rep; and my sales territory was Boca Raton, Florida.

Q. Understood.

Explain for me, if you would, your career with the army.

A. I was a reserve army. I started out in 1970 as a reservist. I was in a direct support unit.

When I went to pharmacy school -- in '71 I believe I started pharmacy school -- I transferred over to a heavy-equipment division in Lima, Ohio, where we did such things, frankly, as --

we did community things, like build ponds and things like that for Future Farmers of America and children's groups.

And you got to imagine: We're in the Midwest. So there's a lot of things like that.

We also did things like diverting rivers and things like that for the Army Corps of Engineers.

I did that until I got my pharmacy degree, at which time I moved back to the Cleveland area.

During that time I was doing retail pharmacy; and they had a hospital unit in Akron, Ohio, which I joined in the medical corps and did not accept an officer's commission or anything like that, because I only had about two more years or so before I was going to be getting out of the service -- but stayed in that medical unit.

We went to Fort Sam Houston. And, you know, that's the kind of thing, every year -- every summer you have to go for two weeks in order to fulfill your responsibility.

Q. So that's the reason for the overlap you talk about in your resume.

You've got 1976 at Hoffmann-LaRoche. So you would have been a reservist, during that same time period, in the army?

A. Exactly.

And in the reserves, it's just like -- you know, you do a weekend a month and you do a summer camp in the summer for two weeks.

Q. Understood.

Just a cautionary note: We're getting to the point where many times you and I are almost talking over each other. You got to make sure you let me finish the question before you begin to respond.

A. Okay.

Q. It feels like a normal conversation; but it's different, because she's got to take everything down.

A. I'm sorry.

Q. All right. So in 1976 you go to Hoffman-LaRoche; and at that time period -- you

mentioned before you were on the sales side?

A. Correct.

Q. And -- oh, actually, let me back up.

During the time period when you were a pharmacist -- 1974 through 1976, working as a pharmacist -- is it true that --

A. You know -- I'm going to interrupt you again. I apologize. But it was a question you asked me earlier about the last time I filled a prescription.

Q. Yes.

A. While I was working, I did do some relief pharmacy work in Florida while I was a sales rep.

Q. So when would that have been?

A. I'm trying to think.

That was probably somewhere around '78 to '80, '81, where I worked outside my territory.

You're not allowed to work in your territory, obviously -- but where I worked outside my territory, filling prescriptions in a retail environment, in Florida, while I was a sales rep at

Hoffmann-LaRoche.

Q. When you were working as a pharmacist during this time period, '74 through some period maybe even in the early '80s, were most prescriptions paid for by patients out of pocket, cash?

A. It depends on where you work.

When I worked in Akron, because of the rubber companies -- Goodyear, etc. -- something in the neighborhood of 80 percent of our prescriptions were filled by cards like PCS.

At that time we had Medimet, which ended up being bought by Medco.

When I worked in Florida, it was a lot less of the cards used to fill prescriptions.

Q. Do you know what percentage of the population had insurance for prescription products during the period when you were working as a pharmacist?

A. At that point?

I honestly couldn't tell you if I had -- I mean, I could guess.

But it would be -- in the Akron area, it could have easily been 80 percent. In the Florida area, I honestly don't know.

Q. All right. Hoffmann-LaRoche, you're there as a sales rep -- pharmaceutical and clinical labs, your resume states.

Now, that part of Hoffmann-LaRoche, was that the -- were you involved in selling pharmaceutical products during that same period?

A. Yes.

Q. Was that blood-testing services?

A. I sold that as well.

Q. What pharmaceutical products did you sell?

A. Valium, Dalmane, Librax, Bactrim, Larotid -- which is amoxicillin -- Trimpex, Zantac.

I'm sure there are more that I'm not remembering. But...

Q. So your responsibilities, when you were a sales rep, were to sell a whole host of different pharmaceutical products to whom? Doctors?

A. Yes.

Q. And the doctors were in what part of the

country?

A. In Florida.

Q. Your resume also talks about taking -- turning a $12,000 clinical lab territory to reach $1 million in sales.

Is that the blood-testing services that Hoffmann-LaRoche would do?

A. Yes, it is.

Q. Now, during this time period when you were at Hoffmann-LaRoche, did you have any responsibility for calling on managed-care customers?

A. At Roche we didn't really have a lot of HMOs or managed-care customers at the time that I was selling. So I did not call on managed care at Roche.

I'm trying to think. We had one managed-care customer, and that was it.

However, I did call on hospitals, etc.; and those really were kind of the beginning of managed care for us.

Q. So a hospital would have, many times, a closed formulary; and you would be calling on a

hospital to present the Hoffmann-LaRoche products?

A. Exactly.

Q. You said that --

A. Now, just so that you know:

There were managed-care clinics in my territory, which I would call on; but that was not the home office -- if that's what you're referring to.

Q. What are the managed-care clinics you're saying you were --

A. Oh, my gosh. I can't remember any of those names.

Q. Who did you report to at Hoffmann-LaRoche when you were on the sales side?

A. I had two bosses: One was Bill Mrazek, who retired while I was there; and the other was Pat Ceralo.

Q. You mentioned that there was one managed-care account that Hoffmann-LaRoche had.

Did Hoffmann-LaRoche have a team that called on that account?

A. Where do I mention that?

Q. That's what you just said a moment ago.
A. No.
Q. Did I misunderstand?
A. There are -- there were managed-care accounts. I didn't call on corporate headquarters.
Q. Do you know if anybody at Hoffmann-LaRoche did?
A. Yes.
Q. Was there a department that was responsible for that?
A. At the time there wasn't a department.
There were individuals that were assigned those responsibilities, and they basically fell upon the individual whose territory the managed-care company was in.
There was an individual in Miami. I do not remember the name of the managed-care company in Miami, but the sales rep that called on them was Les Wachman. And I'm sure he retired before I even got promoted.
Q. All right. And at Hoffmann you say that you developed the Zantac forecast used by senior

management to negotiate marketing goals with Glaxo assigned as a core team member.
A. Correct.
Q. And was that when you became a senior analyst?
A. That was within three months of coming in as a market research analyst.
Q. Zantac is a product that's a stomach medicine; right?
A. Correct.
Q. And it competed with products like Tagamet?
A. Very good. Yes.
Q. And the product was developed by Hoffmann-LaRoche -- by Glaxo?
A. Yes.
Q. And so, Glaxo came to Hoffmann-LaRoche to look for assistance with having a sales force?
A. Yes.
Q. And consistent with, I guess, what you told me before -- was part of what you were doing when you were forecasting looking at how many

individuals that would be involved between Glaxo and Hoffmann-LaRoche in detailing physicians?
A. It was looking at sales trends and providing -- let me clarify.
Your question is about, how did I forecast?
Q. Yes, sir.
A. Okay. It was looking at the trends that were occurring in the marketplace and what were the anticipated sales that we would be getting for Years 2, 3, and 4.
Q. When you were forecasting what sales that Hoffmann-LaRoche might be getting, did you look at how many folks would be involved in detailing?
A. Absolutely.
Q. And why did you do that?
A. Because you want to know what kind of a sales resource is going to be applied to the product.
Q. Were there different forecasts, depending upon how many sales folks were involved?
A. No. There was no need to do that, because

you had one -- one sales force already dedicated to the product. Why would you look at various scenarios?
Q. Understood.
So there was already -- Glaxo already had a sales force, and then they were adding the Hoffmann-LaRoche sales force?
A. Glaxo had a sales force, and Hoffmann-LaRoche provided or had a deal with Glaxo that they would promote the product with so many details a year; and I have no idea what that numbers was.
But they would provide detailing efforts and get paid based on -- and this is really confidential information for the company, which I was not certainly privy to -- but I was led to believe it was based on, you know, a percentage of the sales.
Q. All right. And your resume also states that you spearheaded a four-person task force that developed a forecasting system, resulting in an $8 million inventory reduction.

What type of forecasting system was that?

A. There are several techniques used to forecast.

It's a production forecasting system. Is that what --

Q. So that was production?

A. Right.

Q. And then you've got: "Managed in-house research agency that coordinated and fielded all primary marketing research activities and reduced supplier expenses by 40%."

Is that on the production side?

A. No; that's on the marketing side.

Q. Tell me about that, if you would.

A. Typically, in marketing research -- marketing research, in the pharmaceutical industry, is -- has lots of sources of secondary data on what physicians are doing and regular prescriptions, where prescriptions are going -- unlike the consumer packaged-goods industry.

However, there is a considerable

amount of information that's not captured by these secondary data sources which requires you to go out and do the research itself. Hence, primary research -- for example, doing things like positioning studies or looking at sales aids, if you will, and meeting with doctors and asking them and getting opinions from physicians on the value of the messages, etc., that are provided in the sales aids.

Those are the kinds of things that are more economically done at a convention or something like that, where you've got 10 OBs. You can, you know, give them $500 or something like that to come back and look at this or to go to a hotel room and go through the market research.

We did this in-house and formed our own agency rather than paying someone else to go outside and get those services done.

Q. You said that lots of data is not captured by these data companies, data services?

A. Correct.

Q. What are the companies you're talking about there?

A. IMS. Scott Levin at the time. There was PDS, NDC.

Now, it's -- VariSpan has pulled together a lot of the assets from other companies.

Q. And what type of information don't they capture?

A. Oh, that's a tough question, what they don't capture.

I can tell you what they do capture.

They capture the prescription information, what doctors are writing -- because they actually get a view of the prescriptions.

Companies like PCS, which previously owned a company called "PDS" -- and that's how they got their start, looking at and developing what's today called the "source database," that actually looks at prescription data. And they will go so far as to tell you what the average prescription refill rate looks like, things like that.

So you get a lot of the behavioral kinds of things that are occurring in the market.

What you miss are a lot of the

attitudinal things, like: Why is a doctor doing what a doctor is doing?

Those kinds of questions aren't captured by the audits.

Q. When you were manager of marketing research and information planning, who did you report to?

A. I had two bosses: I reported to the head of marketing research. I also reported --

Q. What was his --

A. Tom Silberg, S-i-l-b-e-r-g.

I also reported to Dr. Bruce Medd, M-e-d-d. He was a physician and head of the professional services -- all the professional, which included marketing services, medical affairs, all those groups.

Q. And why did you leave Hoffmann-LaRoche in 1987?

A. The biggest reason was to move back to the Midwest, and I was being recruited to come to Evansville to do something similar in nature to what I had done at Hoffmann-LaRoche.

Q. 1987, Hoffmann-LaRoche had some hard times and everything. There were some layoffs, I think, in the company.

A. Yes, there were.

Q. Were you part of any head-force reduction?

A. I was there when it happened; but, no.

Actually, that was -- that was a rough time for everybody. But I was not caught up in...

Q. Bristol-Myers was your next company from 1987 to 1993. And there, you worked as the manager of information planning and the manager of worldwide marketing research for the nutritional side of the Bristol-Myers Squibb company; correct?

A. Correct.

Q. And that would include infant formula?

A. Correct.

Q. What other products?

A. Well, I also had women's health-care products --

Q. What --

A. -- until we purchased Squibb.

Once Squibb was bought by Bristol-Myers, they separated the businesses and moved all the pharmaceutical divisions to New Jersey.

But prior to that time, the Mead-Johnson Women's Healthcare Group also was -- I also had that responsibility.

Q. You had -- and let me make sure, first, I understand -- you had responsibility for information planning or worldwide market research for the Mead-Johnson products?

A. Both.

The -- and let me clarify the question, if I can.

Those were two different jobs --

Q. Understood.

A. -- at two different periods of time.

I did the information-planning piece. That was why I came to the company.

When the information planning and the strategic plan was done, they split the company up. At which point I was moved in to be responsible for

worldwide marketing research.

And -- but I still maintained activity for both managed care and women's health-care products on the pharmaceutical side.

Let me further clarify:

There were seven divisions of Bristol-Myers or Mead-Johnson at the time. Only two of which were nutritional: Adult and infant nutritional divisions.

So in order for it to be handled by one person, you couldn't dump five divisions on another individual to have responsibility. So when they split it up, I got those as well.

Q. So -- on your resume it says manager of information planning. It says "United States Pharmaceutical and Nutritional Group."

A. Correct.

Q. And then when you were manager of worldwide market research, which is the '89 through '93, it says "Mead-Johnson Nutritionals."

A. It is nutritionals, but I also had those.

Q. You also had the Mead-Johnson women's

products?

A. For a short period of time. Like I say, until they moved to -- what is it? -- Princeton, New Jersey, yes.

I'm going to say it was probably a year, maybe less than a year. I went through one cycle, one strategic planning cycle, with the women's health-care products.

Q. And what were the Mead-Johnson's women's health-care products that you were involved in?

A. Estrace. They had an ovulation-control product, which -- frankly, the name escapes me.

And I had an analyst -- the major role that I would play with that group was to participate in major -- you know, in big-picture strategic or tactical decisions.

So when the promotional plans were being presented for products, I was there more as an individual to review what was going on -- what was happening, what they were planning to do with the brands -- and ask questions, than anything else.

Q. Any other Mead-Johnson women's products

that you were involved in?
A. No.
Q. At the time that you were at Bristol-Myers Squibb, did you ever have occasion to call on managed-care companies?
A. No.
Q. Did you have occasion to call upon doctors to promote any of the Bristol-Myers Squibb products?
A. To personally make sales calls, are you asking?
Q. Yes, sir.
A. No.
Q. Did you ever oversee a department that was responsible for making sales calls on doctors?
A. No, I did not.
Q. Did you oversee any department that had responsibility for calling on managed-care companies?
A. That depends how you mean the question.
I didn't physically make calls to managed-care customers.
Q. Okay. I understand -- you told me that

Q. What were the products that you were trying to sell to the managed care -- or the managed-care department would be trying to sell into these managed-care customers? These women health products you're talking about?
A. Could be.
Q. Would it be the institutional products as well?
A. Could be, yes.
Q. Not infant formula, though; right?
A. Actually, infant formula as well -- because we looked at managed care as being not just an HMO or a PBM, but the state Medicare, Medicaid.
Medicare, as you know, is a big purchaser of products in long-term-care facilities. And there are programs for women, infant, and children that are done at the state level, funded with Medicaid dollars.
So for those, and doing -- building pricing models and talking about how do you create an appropriate price for -- to make sure that you get these contracts -- and it was looking for things

already.
I'm asking whether you managed any department that called on managed-care customers.
A. That called on them, no.
Q. What your resume says is that you were involved in primary market research for managed health care.
What does that mean?
A. "Managed health care" -- I'm trying to find a way to explain this.
At Bristol-Myers we had, as I said, like seven different divisions that were involved in managed care.
The managed-care group was a centralized group, calling on the large customers -- the HMOs, the PPOs, etc. And we had to look for ways to promote products into those customers.
I would be involved in discussions -- and again, at the strategic level, in decisions and discussions -- about those customers in how to work with them, how to make our basket, if you will, more attractive.

like applying shelf pressure to the drugstore shelf, etc.
Q. What does that mean, "shelf pressure"?
A. Imagine, if you will, that you've got three foot of shelf space allocated by a drugstore for infant formula. If you own two and a half feet of it, that's what I'm calling "shelf pressure."
You know, whatever your space is, you draw attention towards your products.
Q. So would Bristol-Myers Squibb try to get shelf space within various pharmacies or other retail outlets for their products?
A. Absolutely. That's -- every -- all consumer companies work that way.
Q. Do they sign contracts to try to get that shelf space?
A. Yes.
Q. Were you involved in that at all?
A. In the contracting of -- for shelf space? No, not at all.
Q. But were you in meetings and things where that was discussed as part of the strategy?

A. No, not at -- no.
Q. So you don't know whether or not Bristol-Myers sought arrangements with various retailers to have its Mead-Johnson products and, let's say, a preferred shelf position within particular retailers?
A. I don't understand the question.
Q. You don't know whether or not Bristol-Myers entered into agreements with various retailers that had to do with what shelf space they would be provided?
A. I don't have -- I have not personally seen the contracts; but I believe that that was done, yes.
Q. All right.
A. Sorry for that.
Q. Estrace, you mentioned before, was a Bristol-Myers product -- E-s-t-r-a-c-e. That's an estrogen-replacement therapy?
A. Yes.
Q. And is that a generic product?
A. I believe it's generic now. Generically

available.
"Estrace" still is a brand.
Q. It was generically available back at the time that you were at Bristol-Myers Squibb?
A. Not -- I don't think so.
Q. Do you know whether Bristol-Myers Squibb had any contracts that covered Estrace with managed-care organizations?
A. Do not know.
Q. The next thing I see on your resume is Teva Company, formerly "Lemmon Company," in Pennsylvania.
You were there from 1993 to 1997?
A. Yes.
Q. And is Teva largely a generic drug company?
A. Largely it is, yes.
Q. And what did you do at Teva?
A. At Teva I was responsible for marketing. I also was responsible for the managed-care sales force.
Q. How many people were on the Teva

managed-care sales force?
A. Four.
Q. And when you were presenting Teva products, did you personally call on managed care --
A. With my account managers, yes.
I attended meetings. I also attended conventions and things like that, yes.
Q. All right. And with generic products -- with the Teva products, when you were trying to get -- or get in to see managed-care customers -- the products don't go through a P&T review; do they?
A. Typically, no.
Q. The products themselves are assumed to be bioequivalent to the patented product?
A. Typically, yes.
But that's not necessarily the way that people look at the products.
Q. Well, let me ask you this:
The negotiations that would take place with Teva, did any of them -- any of the managed-care negotiations that you were involved in -- when people are looking at those products, is

it basically they're looking at it from a price standpoint?
A. Yes and no. No; I won't say that that's true.
When -- if you are a commodity product where you are in the marketplace with, let's say, 13 other products -- like Captopril -- when Captopril went generic, there were 13 different generic companies in the marketplace. And it truly was a commodity.
When you go out as a first-alone -- let's say, for example, when Andrex goes out with a single product like Prilosec, and they have six months of exclusivity, it's not treated like you would treat a commodity product. And you don't talk to managed care in the same way that you would with a commodity product.
Q. Well, one of the things if -- you've got in your example there, if you've got the first generic product that gets approved, in that situation you do have exclusivity for six months; right?

A. Basically, yes.
Q. And you need to tell --
A. At least six months.
Q. At least six months.
And you need to tell managed care that the product is out there; right?
A. Yes.
Q. And you also have a certain amount of leverage, because there are only two products during that time point; right?
A. Correct.
Q. And did you, when you were at Teva, have any products that were the first product to be approved by the FDA?
A. Several.
Q. Several.
What were those products?
A. Two that come to mind are Clonazepam and Cardizem --
Q. And so --
A. -- which is Ditilizam.
Q. -- were those products -- let's take the

Cardizem example.
If Teva was the first generic product, you would approach various managed-care companies and suggest putting the Teva Cardizem product on the formulary?
A. Um-hum. Correct.
Q. And here's what I'm getting at:
Doesn't it just work as a matter of state law in many places --
A. Absolutely not.
Q. Wait, wait, wait. You got to let me finish the question.
A. I'm sorry.
Q. Okay. And you can educate all of us.
But the question I had is:
Doesn't it work, as a matter of state law or just as a matter of practice, generally, that if somebody would write a prescription for, let's say, a Cardizem -- and unless they, you know, check that box that says, you know, you can't substitute for a generic -- that the product just gets filled with the generic?

A. No.
Q. Why not?
A. Take New Jersey, for example.
New Jersey has a formulary committee. Unless your product is approved by New Jersey, you aren't allowed to sell that product in New Jersey.
Q. So --
A. No matter -- I mean, even if there are 13 generics out there, you can't substitute.
Q. So generic products have to get approved by P&T committees in various states?
A. There's -- there are machinations that you need to go through in order to get approvals. And I would use a different example of a product.
For example, use a -- use a product like Carbamazepine.
Are you familiar with Carbamazepine?
Q. I'm not.
A. Carbamazepine is -- brand name, Tegretol.
Still, a major part of the marketplace is brand because of the nature of the drug.

Even though there are two or three generic companies out there, you still need to go in and promote your product.
Q. Can you think of any examples at Teva where managed care didn't cover a first-approved generic product?
A. Where managed care didn't cover?
Q. Yes.
A. I don't understand your question, because "managed care" is not one company. It's a bunch of little companies.
I'll give you a great example.
I launched Warfarin when I was at Taro. Medco didn't reimburse for generic; they only reimbursed for the brand.
And by the way, Barr had launched Warfarin two years earlier.
Q. Right.
And Barr -- that's what I was -- that's sort of what I was wondering, is: I assume that Medco reimbursed the Barr Warfarin sodium --
A. (Witness shakes head.)

Q. No?
You got to respond, so she can --
A. No.
Finish the question. I'm sorry. I shouldn't have done that.
Q. Yes. What I'm just trying to understand is:
What you're saying is, is that there are many instances where there's a product that's patented; and managed-care companies will decide not to reimburse for a generic product that is the first approved generic product in that particular category?
A. I'm saying that that does occur, yes.
Q. And you gave us this one example with Warfarin.
Can you think of any others?
A. I think that there's -- there's more to it than just looking at what managed care will or will not reimburse for.
There is -- there are other things involved than just that.

Q. Well --
A. Dilantin might be another excellent case.
Q. All right. So there's examples where that happened; but would you agree with me that, generally speaking, managed-care companies will reimburse for generic products?
A. Generally speaking, I will agree with that, yes.
Q. And generally speaking, the discussions and negotiations with managed-care companies about generics typically relate to issues of price, because the products aren't reviewed at the P&T level; right?
A. No, I don't agree with that.
Managed care -- how do I say this?
Managed care doesn't get into price. Managed care looks at what it's reimbursing for the product; and they may set what's known as a "maximum allowable cost" or something like that on a generic product. They don't get into whose generic is going to be used.
Q. So they don't -- that's what I'm

wondering.
A. Your discussions with managed care -- and I'll give you an example -- like, Pharmacy Gold -- would be on quality of the product.
MR. DOBIE: Can you read that -- not that answer, the answer before -- just read that back for me.
I want to make sure I understood Mr. Simon's testimony.
(Whereupon, at this time the referred-to answer was read by the reporter.)
THE WITNESS: And let me clarify that.
They don't typically get involved in whose product is going to be used.
BY MR. DOBIE:
Q. So when you say they don't typically look at price, but they may set a maximum allowable cost, what does that mean?
A. Are you familiar with a federal upper limit?

Q. You got to explain it for the record.
The maximum allowable cost that they may set, what does that mean?
A. The -- when generics come to market, the price of the products are typically lower than the price of the brands.
The AWP, the Average Wholesale Price, may be only 10 percent below the price of the brand; but the actual selling price will be considerably lower than that.
When a generic first comes to marketplace, a reimbursement formula -- and I cannot tell you what everybody's reimbursement formula is -- but a reimbursement formula might be based on the AWP, until the product is generally accepted and available in the marketplace.
Once the product is generally available in the marketplace, the benefit managers will typically go out, and try and find out what is the actual price or what, typically, are pharmacies paying for the product?
And then they will set that, or some

number calculated off of that, as a "maximum allowable cost."

Any prescription that is filled after that time will be based on that "maximum allowable cost" plus a dispensing fee.

Q. So with generic products, once they're out there for a while this "maximum allowable cost" that you're talking about is something that's based upon a review of the marketplace and what people are actually selling the product for?

A. Say that again.

Q. I'm going to strike the question. I think I understood.

What did you mean when you said that managed care doesn't generally get concerned with what product is used?

A. Managed-care companies look at -- for -- as a general rule -- and this is not all of them, by the way -- and I can give you examples of other companies that haven't -- but as a general rule, managed-care companies don't want to dictate that Wal-Mart or any particular customer is going to use

a particular company's generic product.

They're going to dispense what is available in the drugstore, not -- you know, it's not going to be Teva's generic. It could be Myland's generic product.

Q. Okay.

A. And they'll reimburse the same, no matter what.

Q. So in light of that, this is what I'm trying to understand:

If that's the practice -- that you go to a Wal-Mart, and they are not concerned whether it's the Teva generic or the Barr Labs generic -- what are these contracts that are being negotiated between a Teva and a managed-care company?

A. You don't typically have a lot of contracts -- generic companies don't typically have contracts with managed-care companies.

We would have contracts with managed-care companies like a Kaiser, where they're closed-wall.

But the ones -- and I believe -- I

think I understand your question is just those going through retail. So for retail, they typically don't have a lot of those.

Q. I just want to make sure I understand this.

The generic companies will have contracts that cover the closed situations like you described, like a Kaiser -- where they actually, you know, own the hospitals and they control exactly what prescription products are given to their patients --

A. Um-hum.

Q. -- but they won't typically have contracts that tell, for example, a Medco what generic product they're going to dispense --

A. I'm really --

Q. -- when somebody -- let me just finish -- when somebody goes into the Wal-Mart with a pharmacy prescription?

A. I'm really glad you brought that one up.

Yes, I would. I would very definitely have a contract with a Medco.

Q. Why is that?

A. For two reasons -- and herein lies part of the reason with the Warfarin.

Because Medco has two businesses -- they have the benefit-management company as well as the mail-order company -- anybody that can purchase or dispense or anyone that really buys product, per se -- hence, the mail-order business -- you sell to.

And oftentimes, what you'll find is that the two can be tied together when it comes to the brand.

Q. Do you know whether or not -- whether Duramed or Barr had a contract with Medco for Cenestin on the mail-order side of the business?

A. On just the mail-order side of the business?

Q. Yes.

A. I believe that they were talking to Medco, but I don't believe that they picked up a contract on the mail-order side.

Q. Let's go back to my -- what I was trying to ask you, as a general matter --

A. I could be wrong about that. Okay?
Q. Let's set Medco aside. All right?
But I'm going back to your statement that, generally, managed care doesn't care what products -- what generic products are being prescribed. Okay?
I'm trying to understand that, so that we're clear here.
At Teva Pharmaceuticals -- all right? -- are they able, generally, to contract with managed-care companies so that, when somebody goes into a Wal-Mart with a prescription, that the product will be filled with their generic product as opposed to somebody else's generic product?
A. The answer is: We used to be able to, but I don't believe that they do today.
Q. And when was that true, that you used to be able to do that?
A. We used to have a contract with a company, a managed-care company, a Blue Cross Company -- Blue Cross/Blue Shield -- out of Minneapolis, that would actually reimburse at a higher level to the retail

purchaser.
In other words, if a drugstore bought Teva's products or Lemmon product and sold that product -- by using that NDC number when they went for reimbursement from Blue Cross/Blue Shield, they could actually get a higher rebate back.
Q. The retailer would get a higher rebate back?
A. The retailer would get a higher rebate back than if they gave someone who was not an approved.
And in this particular case, Blue Cross/Blue Shield came out. They visited our facilities. They went to Israel to actually inspect where the manufacturing was being done.
Q. And then you said they're no longer doing that.
When did they stop doing that?
A. I couldn't tell you.
Q. Did it happen while you were still there?
A. Oh, absolutely.
Q. So it would have been some point prior

to --
A. I --
Q. -- '97?
A. It was on its way to being -- to going away probably around '97 or '98.
Q. Is that the only contract that you're aware of that was like that?
A. That's the only one that I was aware of.
It doesn't mean we weren't trying to get others to do that; but, yes, that was the only one.
Q. And why were you trying to get others to sign such contracts?
A. Well, we -- we thought it would be great if we could get, you know, improved image for ourselves as being, you know, approved. It looks good.
They've come out and inspected us; and they've said, "We've got a clean bill of health. We look good."
Q. Not only that, they would fill the prescription on a preferred basis with a Teva

product versus another one, I assume?
A. Correct.
Q. And did Teva give the retailer a better price for the product?
A. No.
Q. Just a higher rebate?
A. It would just be a higher rebate from the Blue Cross/Blue Shield.
Q. What products were covered by that?
All Teva products?
A. Yes.
Q. Do you know why they did away with that kind of trade?
A. Because the retailers didn't want them dictating what kind of products they would be stocking. They didn't feel it was fair.
So they did away -- it was -- it could have been a right decision.
Q. Are you aware of any other situation where generic companies enter into contracts -- or -- strike that.
Have you been involved with any other

generic pharmaceutical companies where they enter into contracts with managed-care organizations to provide for rebates or preferred positions, anything like that?

A. Have I been involved with any?

Well, here again, it depends on what you call "managed care."

If you're talking about "group purchasing organizations" and things like that -- absolutely.

If you're talking about a "PBM" -- then, no.

Q. A PBM or an HMO?

A. Repeat the question.

Q. Okay. I'm not talking about "group purchasing organizations," like a group of all hospitals together buying pharmaceuticals and trying to get the best deal. I'm talking about either an HMO or PBM.

Have you been involved in any other situation with any other generic products where the managed-care organizations entered into a contract,

with the generic company, that provided for some sort of a rebate or preferred position for the generic?

A. If you're talking, again, retail -- no.

If you're talking managed care, like VA, Kaiser, or those -- then, absolutely.

Q. All right. So the closed-formulary-type situations?

A. Correct.

Q. But not on a more traditional --

A. Retail, where it goes directly to the managed-care company? No.

Q. Okay.

A. Not that I can remember anyway.

Q. With the generic companies that you've worked with, do the generic companies enter into contracts for formulary placement?

A. At PBMs?

Q. PBMs or HMOs.

A. It's been a while since I've called on the PBMs.

Only for those products that would be

sole source -- you know, first-alone, generics, etc., just those.

I mean, we talked to PCS for -- when we came out with the Ditilizam, twice-a-day-dosage form, to try and get them to put it on and actually do programs for it.

Q. So in those situations where the generic was the sole generic --

A. -- where you were just one or maybe even two, you would talk to them about it.

Or in the case of a -- what they call a "narrow therapeutic index" product, an NTI drug -- such as Warfarin or any blood-thinner, or an anticonvulsant, or things like that -- you would still talk to PBMs to try and move business, yes.

Q. And try to get a rebate contract with them?

A. And try and get a rebate contract, exactly.

Q. Would the rebates be paid in exchange for listing you as the sole source or only generic product or one of two generics?

Was that common in your experience?

A. Sole source -- with managed care? No.

We would do sole-source contracts with -- you know, in the supply channel, but definitely not with...

Q. So you would have sole-source contracts with -- when you say, with a supply channel -- you're talking about with wholesalers?

A. Yes.

Q. So if you're the only source of a generic product, you would give the wholesalers or the pharmaceuticals -- you got to let me finish the question.

A. Okay.

Q. -- you would give them a rebate or a better price?

A. No.

Q. How did it work?

A. I would not -- if I was the only person there, I would be treating my product more like a brand. I would not be giving additional discounts.

Q. I'm confused.

I thought you said you entered into contracts with managed care -- I'm sorry, with these wholesalers.

What were the contracts for, then?

A. For products where you had 13 different competitors.

When you have 10 different people in there selling the same product, then -- and it is looked at as a commodity -- then you have to go and get -- you give them a price concession for a compliance concession.

In other words, you're the only one. Or they're guaranteeing so you much business; and you're guaranteeing them a price, a better price.

Q. Who is the "they" you're referring to?

A. The wholesaler. I'm sorry.

Q. Medi-Span, you were the director of market planning?

A. Basically. The director of marketing.

Q. And it says here that you were working on developing new technology products?

A. Yes.

Q. All right. And one of the things that I took from your report was, you were looking at figuring out whether or not you could sell doctors a product that would be an up-to-date listing of formulary status?

A. Yes.

Q. And that's a product that was never launched; right?

A. The company was sold.

Q. So the answer is: The product has never been launched?

A. The product has never been launched.

Q. Are you aware of any company that has ever launched such a product?

A. Am I aware of any? No, I'm not.

I -- no, I'm not.

Q. Taro Pharmaceuticals, you were there from 1998 through 2000, vice president of Northern America Marketing.

And that's a generic company, but also has Coumadin; is that right?

A. Yes, sir.

Q. What responsibility, if any, did you have at Taro as relates to managed care?

A. The only involvement I had with managed care was getting them to bring an individual in to sell into managed care, as well as to help that individual to prepare a plan for how he would approach the marketplace and to present that to senior management.

Q. And so, he developed the plan for how to sell to managed care the Taro generic products?

A. He developed a plan; and he and I presented the plan to senior management, as to what products and customers we would focus on with regard to managed care.

Q. And what products were you selling to managed care or did you plan on selling to managed care?

A. Well, Taro is a -- mostly a creams and ointments company. So what we were primarily selling was creams and ointments.

We were just starting to become a company that was involved in solid dosage forms. We

had a couple of rather good products, but those were really not the focus.

It was part of our focus to get these customers aware of the fact that we weren't just a creams-and-ointments company; but in the same context, when you're just starting out and you've never had managed care, it was a learning process for everybody -- for management, as well as for the companies that we were calling on.

Q. You said that part of the plan was to decide what products you were going to sell to managed care.

Was the conclusion you were going to sell all the ointments and things to managed care?

A. We were principally going to promote the new products and also offer the older products, but we had never done contracts with these companies. So it was -- you know, we have to initiate contracts.

We have to understand -- the company needs to understand, our distribution department needs to understand -- you know -- how am I going to

ship VA business? Where is VA business going to go? Where is it going to come from? Who is going to order it.

So there were a lot of things like that that we had to learn. And we had to pick the right -- the big customers, the ones that were the most influential and represented the most dollars to us -- and then take the new products -- which represented the more profitable products in the line, and the ones that you want to let people know about the quickest before other competition comes.

I don't know if that answers your question.

Q. I think it does, in part.

Did Taro then go forward and enter into contracts with various PBMs and HMOs?

A. It wasn't PBMs.

Here again, it was primarily people who can purchase product.

Q. The contracts with these generic companies would be largely closed-formulary situations?

A. Or GPOs, or other individuals that can

control or influence compliance.

Q. So is that true with all these generic companies that we're talking about, that the contracts -- let me finish -- that you would be entering into would be with individuals that could enforce compliance -- closed-formulary situations -- you know, the VA, things like that?

A. If I understand your question correctly, that it's people that actually buy product, then the answer is yes.

Q. All right. And not PBMs, but the generic companies -- the contracting is not with PBMs or with HMOs that simply reimburse for product, as opposed to purchase product?

A. That -- that's relatively true.

And I say "relatively" because there are so many of them with mail-order businesses.

Q. And so to the extent that a PBM or an HMO has a mail-order business, those are situations where the generic would be -- the generic companies with which you've had experience would be contracting with them directly because they're

basically a purchaser, just like a Walgreens or anybody else?

A. Absolutely.

Q. Understood.

Sigma-Tau Pharmaceuticals?

A. CIGNA?

Q. "Sigma-Tau Pharmaceuticals."

I'm not a Greek.

A. "Sigma-Tau"?

Q. "Sigma-Tau."

A. I'm sorry.

Q. "Sigma-Tau."

A. Yes.

Q. All right. You worked there from, it says, 2001, at some point, through March of 2002?

A. Basically I was there for a little over a year.

Q. And you were responsible for -- it says, for prescription products?

A. Yes.

Q. And the prescription product that Sigma-Tau --

A. Yes, sir.

Q. -- made was a -- had to do with the end-stage renal dialysis?

A. That was the orphan drug indication that they were approved for.

The original indication for the drug was in infants with failure to thrive, due to inborn errors of metabolism.

Q. It's a nutritional product that you're selling at Sigma-Tau?

A. It's a prescription drug.

It's kind of like a protein, a co-enzyme; and without getting into too much detail, because I want to make sure you understand it, it is the chemical that the body itself typically manufactures that will move fats into different organelles within the cell so that the cell can actually create energy, and then gets rid of the waste products so that they can be excreted.

Without it you die.

Q. Is it an amino acid?

A. Basically.

Q. And it's one of many different products that are given to a patient that's going through renal dialysis?

A. Correct.

Q. And you were defending that product against some generic competition; correct?

A. Not when I started.

I mean, when I actually went to work for the company I was informed that we would not have generic competition because we had orphan drug exclusivity through the year 2006, which ended up being a major surprise when -- you're right -- generics came a month or two after I got there.

Q. In terms of the end-stage renal dialysis that Sigma-Tau was selling into, there's -- what? -- three or four big operators that you would enter into agreements with?

A. That's true.

Q. And did the agreements provide for exclusivity for the Sigma-Tau amino-acid product?

A. No, they did not.

Q. And what happened when the generic

products came on?

A. We were pushed for much lower pricing, which we had to give in order to keep the business.

Q. Was there any advantage of your products versus the generics, or from the FDA's point of view were the products simply substitutable?

A. That's an interesting question.

From the FDA's perception, they have left it more up to CMS. I don't know if CMS was referred to in Dr. Kolassa's report or not; but it's the Center for Medicare/Medicaid, something or other. But it's the old HCFA, Health Care Financing Administration.

We approached the FDA in order to get approval for the indications of the product and for use of the product, so that it would be reimbursable through Medicare and Medicaid -- well, Medicare specifically.

And the bottom line is: We ended up getting -- or they -- this was after I left -- they ended up getting approval for the indications, but the actual payment of the product was still up in

the air with regard to whose they'd pay for.

So they basically will pay for the generic or the brand.

So any marketing efforts that would be put into the brand really is the only difference between the brand and the generic, as far as the FDA is concerned.

Q. And Medicare reimburses for all of this treatment after the first year; right?

A. For the most part, yes.

Q. So this is not a situation where you're contracting with managed-care companies in connection with entering into some contracts for the Sigma-Tau product?

A. Contracting with them, no.

Q. And then in your report, Exhibit 1075 --

MR. PARKER: Gordon, are you done with background now?

MR. DOBIE: No. I want to do his consulting. And then can we take a break?

MR. PARKER: Okay.

Q. You mentioned that you've consulted with a

number of different pharmaceutical companies.

You've got "Odyssey Pharmaceuticals."

Let's talk about that. What have you done for them?

A. Odyssey was -- and the first couple of companies that you see on there are related.

Odyssey is the branded division of Sidmak. Sidmak was looking to bring a couple of products to market.

My consulting with them was principally along the lines of looking for and interviewing companies for a sales force, and with regard to the marketing of the couple of products that they were going to bring to the market, first off.

And this was -- was not strategic in nature at all. It was mostly looking at and coming up with appropriate messages for their sales materials and advertising materials.

Q. Odyssey, that's a biotech company; right?

A. Odyssey is -- no, it's not.

They are a branded division, now, of

Sidmak -- which is a generic company, and they were just purchased by Plava.

Q. Right. Did Odyssey ever bring any products to market?

A. Oh, yes. They're in market right now.

Q. What are they bringing to market?

A. I don't even remember.

I do know that they're selling, right now -- it's a urinary/continence product that they purchased from Merck. And I cannot remember the name.

Q. But are there products that you worked on --

A. That one.

Q. You did work on that?

A. Just -- just for -- just to review the promotions. That's it.

Q. So you reviewed the promotional material for the Odyssey urinary/continence product?

A. And there's another product that was competitive to Sandos's neoral -- "Cyclosporine A" -- which they brought to market as well.

And that one, I worked on their -- on the development of their promotional materials.

Q. Okay.

A. In other words, looking into the market, seeing what -- you know, patients -- etc.

Q. "Pharmacia," what did you do for them?

A. Pharmacia was a project where they wanted to understand the impact of USP and changes to the USP with regard to generics.

By the way, I have confidentiality agreements with all these companies. Am I --

MR. DOBIE: You can put -- the whole deposition can be designated "confidential" and "highly confidential," whatever is appropriate.

THE WITNESS: Does that cover me with confidentiality.

MR. PARKER: As between our two companies, it covers.

I'm not sure it helps him with those third parties.

I wonder if we can, you know, be real discreet about what you say so we don't have

a -- I mean, it's probably not the nitty-gritty --

MR. DOBIE: I'm not going to get into it in any great detail.

But I'm just trying to understand what you did, because --

A. They wanted to understand the impact of the United States Pharmacopoeia on their product line in generics.

Q. They have a generic product line?

A. They have a generic product line, but that's not what they were looking to find out.

They were looking to find out how the USP would impact -- or changes to the USP would impact the introduction by someone else of a generic of their product.

Q. When did you do that work?

A. Four or five months ago, three months ago.

Q. Who did you report to at Pharmacia on that?

A. I worked with another consultant, Ed Thwaite.

Q. Who at Pharmacia?

A. Don't know.

I shouldn't say that.

I don't remember.

Q. But Pharmacia was looking at how competition, generic competition, could impact its branded product?

A. Basically.

Q. You were looking at how it would be impacted.

Were you asked to figure out how to defend the branded product?

A. No.

Q. When you were at Sigma-Tau --

A. I was asked to look at what the impact would be of the USP, or a change in USP, on the development of a generic product.

That's basically it.

Q. At Sigma-Tau, just to go back to that -- when you say: "Successfully defended our major brand against 3 generic entrants in our primary market" -- how did you successfully defend it?

A. By value-added services. By going in and discussing with them the kinds of things that we can bring to them, like -- there are mechanisms that you have to go through in order to decide whether a patient is a candidate for the product.

There are things called "fiscal intermediaries," which I think you are familiar with -- you seem to be familiar with -- the Medicare process.

They make their own decisions. So you have to put together decision trees so that they understand, when they submit the bill to the fiscal intermediary, what kinds of things need to be included on that bill in order to get paid. And they can change over time.

So these are the kinds of value-added services that we would provide that are not provided by a generic manufacturer.

And the generic manufacturer -- and it's kind of interesting. The generic manufacturer does not have in their package insert the indication for use in dialysis, but that's where all of it's

being bought and used.

So whether they were or were not allowed to do these kinds of things, I don't know.

You know, whether that would be perceived in some way by the FDA as, you know, "You guys don't have that indication. Why are you doing this?" We could do those things.

So that's primarily how we kept the business.

Q. Did you point out, to the companies that were purchasing the Sigma Tau product, the fact that Sigma Tau's amino-acid supplement product had the indications and the generics did not?

A. Yes. And they didn't seem to care.

Q. Was it all three generics that didn't have the indications?

A. No generic can have that orphan drug indication.

Q. Oh, I see. It's the orphan drug indication, okay.

But the FDA has determined that the products are bioequivalent?

A. The drugs are deemed bioequivalent.

Q. What did you do for Sidmak? Is that the same thing as what we're talking about with Odyssey?

A. Pretty much, yes.

Q. Anything else?

A. When you get to Medirex, Medirex is a re-packager that was also owned by Sidmak.

And it was interesting. I was not brought into that as a result of Sidmak, so much.

They were looking to find ways either to sell the business, because it was not meeting their expectations, or to find new customers.

So I had to go out and talk to other generic companies, primarily, as to find out what the interest would be in this kind of a re-packager; and the problem that the company had was such that there was nobody with a great amount of interest.

So -- and, frankly, there was nobody that was interested in buying the company. So they folded up shop.

Q. "PoliChem," that's a veterinary medicine company in Europe?

A. No, they're not veterinary.

"PoliChem" is a manufacturer in Europe. They were looking to bring some molecules into the United States, and they were looking for me to give them an assessment of what the value of these products were in the United States, as well as to assess what customers we might approach in developing alliances.

Q. Did any of that involve managed care?

A. If you're talking GPOs, yes.

Q. Okay.

A. If you're talking PBMs, no.

Q. Or HMOs that aren't buying the product directly, it didn't involve that either?

A. That aren't buying direct, no.

Q. "No," it did not involve?

A. It did not include any of those.

Q. Understood.

"Forrest Labs," what did you do for them?

A. Forrest Labs was looking at a -- at developing a portfolio of products.

They were looking at, what would be the impact of several different products; and they wanted me to forecast those generics for, like, the next three or four years so that they could prioritize their activities, their development activities, on generic products.

Q. Did any of that involve managed care?

A. No.

Q. How about "Astra/Zeneca"; what did you do for them?

A. AstraZeneca -- AstraZeneca actually -- that was an interesting -- AstraZeneca was helping them to prepare for Prilosec going generic.

And I participated.

And here again, I have a confidentiality agreement with them. So I can't get into too much detail; but I will tell you it included me preparing an assessment of what their competition would do, how they would probably do it, and what would be the impact.

And that did include an assessment of managed care.

Q. Well, AstraZeneca -- their product, Prilosec, is a product that they had on a number of different exclusives with managed care; right?

A. Yes.

Q. Okay.

A. What do you mean by "exclusives"?

Q. They had contracts with various managed-care organizations that Prilosec would be the only PPI on their formulary.

A. I was not aware of that.

Q. Okay.

A. That could be, but I was not aware of that.

Q. All right. So that wasn't part of your analysis?

A. No, it was not.

Q. All right. So when you say you were looking at managed care for AstraZeneca on Prilosec, what were you doing?

A. Looking at how the generic companies would be impacted, how the PBMs would make a decision, when and where they would make the choice that you

had to go to a generic -- those kinds of things.

Q. Understood.

Who did you report to at AstraZeneca about that?

A. My primary contact was Andy Stoutberg, who is still there.

Q. And then the last one you got on consulting here is "Ruane, Cunniff & Company."

A. And they were looking for a -- and that was just a day project.

That was an assessment of the distribution marketplace; and it was more as a focus group, if you will.

I wasn't in a focus group. It was more a personal interview.

They spent a good day on the phone with me, to get to understand the distribution channel and how products moved through the distribution channel and where the moneys come from through the distribution channel -- as well as, where are the actual source of funds, you know, for a company -- for a wholesaler who works on margins

of, like, 1 and 2 percent, where do they really make their money?

Q. With AstraZeneca and the PPI, the contemplated introduction of a generic -- were they working to figure out how they would defend the brand in the face of generic competition?

A. Yes, sir.

Q. Were they also looking at how they were going to defend the brand, as it relates to their other competitors in the category -- the Prevacids, the Protonixes, and the other products in the PPI category?

A. That was beyond the scope of my project.

I'm certain they were doing it, only because of the information that they provided me; but it's not something that I was involved in.

MR. DOBIE: Why don't we take that break?

VIDEOGRAPHER: The time is 10:48. We are off the record.

(A recess was taken.)

VIDEOGRAPHER: The time is 10:59.

We're back on the record.
BY MR. DOBIE:
Q. Mr. Simon, I had some follow-up questions about some of the things we were talking about.
You mentioned Warfarin sodium as a product that had been approved by the FDA but not immediately, I guess, reimbursed by various managed-care organizations.
Do you recall that testimony, generally?
A. Yes.
Q. Warfarin sodium, I think you also mentioned, is a narrow therapeutic indication product; right?
A. Yes.
Q. It was a product that a number of state board of pharmacies concluded that the product could not be substituted until they had reviewed it and approved it as a true substitutable product for the branded; correct?
A. Correct.
Q. And isn't that one of the reasons why

various managed-care organizations didn't immediately put it on formulary?
A. I honestly couldn't tell you.
Q. Okay.
A. And I couldn't tell you that a lot of them didn't have it on formulary.
Are you speaking PBMs at this point?
Q. I was following up on your -- were you talking about PBMs when we were talking about before?
A. If your question, though, is: Was it on formularies? It very well could have been on PBM formularies.
Q. All right. In the situation with Zantac and Glaxo, do you know whether Roche detailed Zantac heavily?
A. Yes.
Q. Do you know whether they increased the details in order to attempt to increase sales? Was that the goal?
A. I would suspect that, yes.
Q. And then when you were with Bristol-Myers

Squibb, with the Estrace product -- were you involved at all with how Estrace was positioned in the marketplace?
A. No.
Q. Do you know what advantages, if any, Estrace had over Premarin or Cenestin?
A. I do not.
And Cenestin wasn't a product then, either.
Q. Let's look at your report, Exhibit 1075; and I'm interested in page 3 of the report.
A. Can I make a comment before we start?
There are a couple of things in here that I want to make sure are more clear -- specifically, on page 13 where it says "KOLASSA 30." That's Dr. Kolassa's report at page 30.
Q. Okay.
A. And on Page No. 11, the sentence that starts: "The fact that Cenestin has similar market shares" -- I mean similar to Premarin.
I don't know how you read that.
Q. You want it to read, the fact that

Cenestin has similar marketshares to Premarin?
A. The fact that Cenestin and Premarin have similar marketshares, etc.
Q. Anything else?
A. That's it.
Q. Okay.
A. I apologize.
Back to your question on page 3.
Q. No, no problem at all.
Under your heading, it says: "Cenestin is not a 'me-also' product."
A. A "'me-almost' product"?
Q. Is not a "'me-almost' product"?
A. Correct.
Q. Let me ask you first:
As I understand this, you have got a view that "Cenestin's pharmacokinetic profile and improved dosage uniformity compare favorably to Premarin"; correct?
A. Yes.
Q. And that's based upon various tests and things that Duramed has done on those products?

A. That's based on the promotional materials that Cenestin is using, as well as -- yes -- tests that have been done, like dissolution tests.

Q. Let me ask you about one of those promotional materials.

A. And they are really hard to read.

Q. Yeah.

Here is Exhibit 744.

Sir, for the record, Exhibit 744 is one of the detail aids that Solvay produced in the litigation.

Is this one of the documents that you reviewed in connection with your service as an expert for Duramed?

A. I am not certain, but it looks familiar.

Q. Among other things, it discusses the various pharmacokinetic and pharmo-dynamic features of Cenestin; right?

A. Where is that?

Q. It begins, I think, on page SO2531.

A. Okay.

Q. And there's a "Key Feature."

It talks about how blood levels for some estrogens may vary; and Cenestin, under "Key Benefit," delivers smooth, steady release of conjugated estrogens -- and so on.

A. Yes, sir.

Q. And there are a few different pages.

Do you understand that this is the type of detail aid that would actually be given to the sales force for them to call on physicians?

A. Um-hum. Yes.

Q. And the benefits that you're describing are -- some of those benefits, the smooth release of the estrogen -- smooth, steady release of conjugated estrogens and blood levels -- improving blood level for the estrogen from dose to dose -- those are some of the advantages of the Cenestin product; right?

A. Yes.

Q. All right. Now, let me draw your attention to page SO2537. And on the right-hand column, there is a black box.

And if you look at the very last paragraph, it says that if a doctor asks to see the

clinical benefits of these pharmacokinetic data, you should point out that the clinical significance has not yet been determined.

Do you see that?

A. Yes, I do.

Q. And it says, "However, you may want to point out that Duramed and Solvay have initiated a comparative clinical trial."

A. Yes.

Q. Right.

So the "pharmacokinetic benefit" that is referenced is something that, the clinical significance of that still hasn't been determined; right?

A. In a clinical study, it has not been determined.

Q. Right. So they take a Cenestin pill, and they drop it in distilled water, and they see that the product has improved dissolution profile versus the Premarin study; correct?

A. Yes.

Q. What it doesn't do, what hasn't been

determined, is that the product actually makes people feel better in a clinical sense; right?

That dissolution profile hasn't been linked to, actually, a clinical difference for patients; right? That's what that means?

A. That's what I think they're saying, yes.

Q. All right. And the water -- maybe the water feels better. There is a smoother dissolution.

But it has never been determined that it makes any difference in the real world to patients; right?

A. In terms of the dissolution studies you're referring to, correct.

What it speaks about is not something that has been clinically evaluated.

Q. So when we're talking about the benefit or the fact that Cenestin compares favorably to Premarin, this is based upon studies for which there has not been a determination that there is a clinical significance; correct?

A. Correct.

Q. Now, the analogy that you draw in your report is -- you say that Amoxicillin was launched at price parity to Ampicillin; and that even though both products have the same indication, side effects, and same antibiotic spectrum, Amoxicillin has a better pharmacokinetic profile and obtained a higher marketshare with a higher price?

A. Correct.

Q. All right. And that's the analogy that you're using with Cenestin; right?

That's a good comparison, in your view?

A. That is a comparison where a pharmacokinetic difference was used to sell a product.

Q. Right. I mean, in fact, Amoxicillin was a product that was a three-time-a-day product, versus Ampicillin being a four-time-a-day product?

A. Correct.

Q. And Amoxicillin was known to absorb better than Ampicillin?

A. Correct.

Q. And it was also something that could be taken on a full or an empty stomach; right?

A. Correct.

Q. And so, those were all benefits that helped Amoxicillin sell over Ampicillin and charge a premium price?

A. Correct.

Q. And Amoxicillin was launched by Beecham?

A. Originally, yes.

Q. And they had a large sales force?

A. This was back before I even got into the business.

I can't tell you that.

Q. Mid-'70s or something?

A. Early '70s.

I can tell you that I sold Larotid, which was an Amoxicillin product, to physicians.

Q. All right. Then on page 4, we've got: "Drugs are not always, or even usually, launched only after obtaining approval for all possible indications."

A. Where are we? Page 4?

Q. Yes, sir; at the top.

A. Yes, sir.

Q. Your heading "B."

A. Yes, sir.

Q. And the point you're making here is that, even though Cenestin did not have an osteoporosis indication -- unlike Premarin and the other products in the estrogen-replacement-therapy category -- that it's not unusual for a product to come out with one indication and later get others; right?

A. That's correct.

Q. All right. And the example that you have here is Intron A?

A. Correct.

Q. And Intron A is a product that was made by Schering?

A. Yes.

Q. And it is a -- I hope I've got this right -- an interferon alpha-2B?

A. Yes.

Q. It's used --

A. I'm not sure about the "B"; but, yes, it's

an interferon alpha.

Q. It's an immune system product?

A. Exactly.

Q. And when it was launched, it was launched for -- as you note here -- with the only two indications being rheumatoid and osteoarthritis?

A. No; that's Celebrex.

Q. I'm sorry.

It was launched with "Condyloma" --

A. "Condyloma."

Q. -- "Condyloma" and "Kaposis sarcoma"?

A. Yes.

Q. And isn't it true that, even though it was only launched for those two indications, that the product wasn't really successful until it got approval for hepatitis?

A. I don't know. I do not know.

MR. DOBIE: Let me show you something.

Let's mark this as the next exhibit.

Mark this as 1027, I think -- 1077.

(Defendant's Exhibit Number 1077 was

marked for identification.)
BY MR. DOBIE:
Q. I hand you what has been marked as Exhibit 1077; and as indicated here, Intron A was originally -- the first indication was hairy cell leukemia in 1986.
In '88 it got approval for condylomata. I don't even know how to pronounce that -- c-o-n-d-y-l-o-m-a-t-a.
And then in November of '88, it got approval for Kaposi's sarcoma.
Do you see that?
A. Yes, I do.
Q. And then, you see where it was approved for hepatitis in July of 1992?
A. Yes, I do.
You've got February '91.
Q. Yes.
A. Hepatitis B in '92.
Q. And, sir, you don't know whether or not the sales of this product didn't take off until Hepatitis C was approved; do you?

A. I do not know about the sales of this product.
Q. Do you know how the sales of this product, Intron A, compare to the other product that is indicated on Exhibit 1077, which is --
A. Roferon?
Q. -- Roferon-A?
A. I do not -- I have not followed this product, no.
Q. All right. Roferon-A is an interfon alpha-2A. It's indicated for hairy cell leukemia, but it does not have the -- it also has the indication for Kaposi's sarcoma. It has indication for Hepatitis B in Canada and in Europe.
But do you know what the sales were of Roferon without the Hepatitis C indication?
A. No, I do not.
Q. Would it surprise you to learn that they were significantly less than the Inton A sales?
A. It would not surprise me at all.
Q. All right.
A. I have not looked at...

Q. You haven't looked at that?
A. Correct.
Q. All right. Well, in your report you basically are saying that it may not be necessary to have all indications to launch a product.
But you'd agree with me that having more indications can significantly impact the sales of a product; correct?
A. I don't understand.
Having more indications, having every indication that is possible to have, would be very beneficial. I state this in my report. And that, I have no doubt.
But it doesn't mean that you don't launch a product because you don't have every indication, as is example with Celebrex.
Celebrex is getting additional indications as time goes on, but their original indications for rheumatoid and osteoarthritis are the ones they came to market with.
Q. We'll come back to Celebrex in just a minute.

But you'd agree with me that, yes, companies do launch products without all indications, but that the lack of an FDA-approved indication could significantly impact sales?
A. No, I won't say that at all.
Q. Okay.
A. I would say that it depends on what the value is of that indication.
If you come out with a product for -- if you start adding indications that are nonsense for the product later on, what difference does that make?
A great example would be the Sigma-Tau product. When the product was brought to market, it was all orphan drug indications.
Q. But the example you picked in your report, sir, was Intron A. All right?
A. I picked two examples: Celebrex and Intron A, yes.
Q. All right. And with Intron A, you would agree with me that you simply do not know whether or not additional indications that were approved for

Intron A are the reason why the sales ultimately took off for the product?

A. I am not putting both of those facts together.

The question is -- or the implication from the report was that -- it didn't come with all of its indications, how would it do well?

The point is that a lot of drugs come to the market without all of the indications.

Q. Okay.

A. I mean -- this is -- what I'm presenting here doesn't discuss anything about sales value.

Q. Well, that's what I'm asking; and maybe we can get on the same page.

What you're saying is, is that it's common to launch a product without all indications; right?

A. That's what I'm saying.

Q. You're not saying that having all indications doesn't have economic value?

A. I'm not saying that.

Q. Understood.

And as it relates to Cenestin and the osteoporosis indication, not having an osteoporosis indication -- I mean, having -- let me restate it.

As it relates to Cenestin, having an osteoporosis indication could have economic value; correct?

A. I would say yes; correct.

Q. All right. Now, let's talk about Celebrex.

Celebrex is a Cox-2 inhibitor; correct?

A. Correct.

Q. It competes with Vioxx?

A. It competes with NSAIDs and Vioxx.

Q. And it's a product that was made by Pharmacia, a company that you had some familiarity with -- and now owned, I guess, by Searle -- or Searle, now owned by Pharmacia?

A. Correct.

Q. And Celebrex was launched with its two most important indications first; was it not?

Rheumatoid and osteoarthritis?

A. I don't know that.

I know that, to date, those would be the two most important indications.

Q. Do you also know that Celebrex was launched with a huge sales force?

It was Searle along with Pfizer working together?

A. Yes.

Q. Something like --

VIDEOGRAPHER: I need to change tapes.

MR. DOBIE: Okay. Let me just -- do I have one question, or no?

VIDEOGRAPHER: Go ahead.

Q. -- something like 4,000 reps to launch Celebrex?

A. Was it Searle and Pfizer?

Q. (Counsel nods head.)

A. Okay. It could be.

Q. And do you know whether they launched -- over 3,000 of these sales reps launched Celebrex in either -- when they were promoting it, it was

detailed in either the first or second detail position?

A. I don't know that, but that would not surprise me.

Q. And would you agree with me that having that big sales force like that and having launched Celebrex with the two most important indications first, that that could be one of the reasons why that product was very successful coming right out of the box?

A. I would say that that's probably very important, yes.

MR. DOBIE: All right. Let's change the tapes. Thanks.

VIDEOGRAPHER: The time is 11:22. This is the end of Tape No. 1.

We're going off the record and on to Tape No. 2.

(A recess was taken.)

VIDEOGRAPHER: The time is 11:23. This is the beginning of Tape No. 2.

We're back on the record.

BY MR. DOBIE:

Q. On page 4, the heading: "Cenestin was offered in the necessary strengths" -- again, this is a place where you discuss how Cenestin was launched with a .625 milligram and .9 dose.

But the 1.25 dose was released within eight months of the product launch; right?

A. Yes.

Q. Now, let me ask you about that.

The time of launch, Cenestin only had this .625 and the .9 -- which were about 73 percent of prescriptions written; correct?

A. Okay. I think that's about right.

Q. Here's what I'm wondering: Later on in your report you talk about spillover.

A. Correct.

Q. Do you think there could be a spillover -- if a doctor learned that Cenestin was not offered in a 1.25 milligram strength, that he might be hesitant to prescribe Cenestin at the lower dosage?

A. I honestly couldn't answer that question.

My experience is that a physician

that gets a product that is working, if he wants to adjust the dose, always has the option of giving two tablets to the patient and upping the dose.

But it certainly would be easier to take one pill instead of two.

Q. Right.

A. I --

Q. Easier and less expensive; right?

I mean, taking two tablets is going to cost you twice the price -- assuming that the 1.25 is less expensive.

And they usually are; right?

A. I -- what do you mean, "less expensive"?

Q. Well, did you look at the prices, for example, for Cenestin and Premarin, and whether, economically, it makes sense for somebody to take two Cenestin tablets?

A. Twice as expensive to who?

Q. For the patient or for the managed-care organization, whoever is paying for the product.

A. I -- the patient is not going to see any difference in price on managed care. The patient is

going to pay the same price.

Q. How about managed care?

A. Managed care doesn't pay for the product. The patient pays for the product.

Q. Are you aware of any physicians that are -- or managed-care organizations -- that told Duramed that they were -- that it was okay with them to go ahead and buy two tablets if they needed to titrate up, as opposed to --

A. No. Am I aware of that? Absolutely not.

Q. Okay.

A. And is it the best of all possible scenarios to be in? I wouldn't say that either.

Q. Okay.

A. What I would say is that the products -- by the time they really got out and were selling these products, they had the 1.25-milligram tablet within eight months.

So they had all the strengths when they were promoting these doctors, within eight months -- and certainly for the majority of the year 2000.

Q. All right. Have you looked at the documents about various managed-care organizations that were approached in '99 and said that they would not consider Cenestin until they obtained approval for the 1.25?

A. I am -- is there any one in particular you're referring to?

Q. Well, there's -- I think there's a number of them that are out there.

But are there any that you're familiar with, having reviewed the documents?

A. I was familiar with the documents; and I saw that PCS put it on at least their open formularies, even without it.

Q. And what are you referring to when you say PCS put them on their open formularies?

A. The open formularies that PCS offers or has, they offered the product.

Now, I don't know if that was in '99 or before the 1.25. I think it was before the 1.25 as well.

Q. So your understanding is that the 1.25

wasn't an issue for PCS.

Are there any others that you can refer to?

A. I cannot.

I can tell you, I do remember reading where some of the managed-care organizations did mention the lack of a 1.25 milligram. Yes.

Q. Let's look at page 5 of your report and heading "D." This is the discussion of the "Class Effect."

A. Um-hum.

Q. And you talk about how class effects are an integral part of a pharmacist's education, and so on.

Do you teach pharmacists?

A. No.

Q. Have you ever taught pharmacists?

A. Yes.

Q. When?

A. As a -- when I was in my last year of pharmacy school, I taught the manufacturing lab at Ohio Northern University.

Q. When was the last time --

A. That was in 1974, a long time ago.

Q. When was the last time you looked at a curriculum for a pharmacist's education?

A. It has been a long time.

Q. Do you consider yourself an educator?

A. No, I do not.

Q. Have you written, at all, any publications?

A. No, I have not.

Q. How about books, anything like that?

A. No, sir.

Q. Did you do a thesis in college?

A. No, sir.

Q. Are you familiar with the pharmaceutical-industry educational literature?

A. What do you mean?

Q. Could you name, for example, for me, the leading pharmaceutical educational journals?

A. "Journals"?

Q. Journals, magazines, sources.

A. If you're speaking peer-reviewed things,

like disease and therapeutics -- I do not typically read those. So I --

Q. How about things that are specifically related to pharmacists?

A. Like?

Q. American Journal of Pharmaceutical Education.

A. Pharmaceutical education journals? No, I would not read that.

Q. Okay.

A. Trade journals about what's going on in the industry -- drug topics, U.S. pharmacists, those kinds of things -- yes.

Q. All right. So when you say in your report this is how it's taught, what you're talking about is: How this is how it was taught to you back at Northern Ohio in 1974?

A. That's correct.

Q. All right. And the way it was taught -- was it not? -- was that you would start out with an overview of the class of pharmaceutical products.

So if, for example, on a particular

day, if you were talking about -- you list here Benzodiazepines -- you would start out with a --

A. Pretty good.

Q. -- with a discussion of that class of products, that category of products, Benzodiazepines.

And then -- right? That's how it would go?

But then, isn't the next part -- I mean, that might be -- what? -- ten minutes, fifteen minutes. And then it would describe, generally, those are the sedatives. And then you would learn all of the differences between the products within a class.

Isn't that how it's typically taught?

A. Typically -- well, certainly not fifteen minutes.

The way that I was taught was to look at a class of drugs -- let's say, Benzodiazepines. And you would spend a day talking about it in your pharmacology.

You'd also talk about how it

interacts physically in your physiology class.

So you might be covering that same class of products in two or even three different classes.

And when it got to antibiotics, it was even -- even -- you know, you'd bring in microbiology, etc.

But, yes, you would learn -- you would start with learning the class of drugs. Then you would key in on the pharmacokinetics of the drugs and what made the drugs different.

For example, if -- to use Benzodiazepines -- if I'm looking at a product like Valium, I would learn about Valium and all of its six or seven different active metabolites.

And I would learn about structure-activity relationships, which is what you're talking about in medicinal chemistry -- which is another class.

That would then talk about how are these drugs and what are the differences in the drugs -- what do those differences mean,

pharmacokinetically?

Is that what you're asking?

Q. Yes. I think we're on the same page.

In other words, you learn about the class of the products, generally, and how the molecules tic, as it were.

But then you do -- you're not denying that there's differences within Benzodiazepines, for example -- I mean, significant, huge differences? And doctors and managed-care organizations look at those products differently within that class?

A. I would say that you're correct.

Q. So, for example, you've got Valium here; and you've got Librium and your list of Benzodiazepines in your report.

Those are both products made by Roche; right?

A. Um-hum. Yes.

Q. And they also make other products, like Dalmane and Versed; right?

A. Correct.

Q. And so they've got a whole group of

different Benzodiazepines that are used for different purposes?

A. Correct.

Q. I mean, they're all sedatives. But some of them, like a Librium, is not nearly as strong as something like a Versed; right?

A. Well, first, a Versed is an injectable. Versed is a water-soluble Benzodiazepine.

It does the same thing as Valium. The only difference is that they use it as an injectable because it's -- does not have the same sting as Valium injectable does.

It's a much preferred drug.

Also, it causes a little bit different amnesiac effect.

Q. Right. It's usually the amnesias; right?

A. But every single thing that Versed does, Valium does.

Q. Isn't there a lot of difference within Benzodiazepines, just in terms of the strength and the power of the products?

A. There's differences with respect to -- the

answer, in a glib way, is for me to easily say yes.

But there's more to it than that.

Q. I guess that's what I'm saying: There's more to it.

In other words, you're talking about class effect -- okay? -- in this section of your report.

And I understand that they're all sedatives. But on the other hand, there are big differences in products.

Halcion is a Benzodiazepine. That's called "the hammer"; right? That's the nickname for that product?

A. I don't know that, but you could be right.

Q. And some of the products, there are nicknames for these products in the market.

"Rufies," that's a product that you see that -- there's a whole criminal drug problem with rufies.

A. But the point is, if I understand your question: The drugs themselves still are going to impact that same receptor site. They're still going

to do pretty much the same thing.
There is a difference with which -- at which time it's absorbed. There are pharmacokinetic differences.
You know, one might be absorbed faster than the other. One might get out of the body -- for example, you mentioned Dalmane and Halcion.
Q. Right.
A. Halcion has a very short duration of action. It's eliminated. There's -- pharmacokinetically, it's eliminated quicker. So it's out of the body quicker than Dalmane.
But they're both used for the same purpose.
Q. Right. Well, they can be treated for anxiety.
Some of these products are actually indicated for epilepsy, though; right?
A. That's true.
Q. Some of these products are considered minor tranquilizers, and some of them are considered

hypnotics; right?
A. That's -- yes.
Q. And a doctor and a pharmacist -- when they're learning about these different products, they learn about the differences in those products.
And those differences can have a real-world impact in how they're prescribed; right?
A. They learn that they all have a particular similar action: This one may be stronger in this way. This one may be stronger in this way.
You're absolutely right.
You could use -- as a matter of fact, Benedryl -- case in point: They used the side effect of Benedryl as an over-the-counter sleep aid.
But the point is that the drugs themselves do the same things. One may have a stronger action this way than the other, because it's a different type -- a different molecule. It's turned different. It does something different.
But they're still interacting at the same receptor site.
Q. I'm not disagreeing with you on that.

I guess what I'm saying is: The differences in these products, within the class, impact physicians' prescribing behavior; right?
A. Yes.
Q. And those differences will also impact the sales of the product; right?
A. Yes. And the way they're sold to the physicians and -- exactly.
Q. Sure.
The other thing I wanted to ask you about in the same section on the class effect is:
You have a discussion about how Wyeth's birth-control products are prescribed by physicians to treat acne, even though they don't have the indication on their package insert.
A. Correct.
Q. Isn't it true that the acne benefit for birth-control products is something that has been in the medical literature since the 1970s?
A. I don't know that, but it's possible.
Q. And is it also possible that doctors could be prescribing Wyeth birth-control products for

having the incidental benefit of treating the acne based upon scientific studies like that and having 20 or so years of experience in doing so?
A. That's an interesting premise. Let me see if I understand the question.
What you're saying is that, because it has been in the literature the doctors could assume that other products that aren't necessarily indicated for treatment of acne could also be used.
Q. No. What I'm saying is this:
You're saying in your report that doctors just assume class effect; and so doctors would assume that Cenestin would have the osteoporosis indication.
And what I'm suggesting the difference between the acne situation and Cenestin, is that doctors have been prescribing -- they may see the same woman for, you know, 10 or 15 years; have prescribed her the birth-control pills; learned that, in fact, in the real world that the product did provide her with an acne benefit.
That's not the same thing -- you

would agree with me, would you not? -- as a doctor looking at Cenestin, a brand-new product on market -- they don't have experience -- they would not have experience that the product -- that Cenestin did, in fact, provide an osteoporosis benefit?

A. I don't know that that's true.

I certainly will agree with you that, in terms of them having experience with conception-control products, that they have seen the benefit and because of that -- their empirical, if you will, experience -- that they've decided that they can do this.

I can tell you that I was told by a sales rep that, you know, doctors are indeed making that assumption. They're basically telling them, "Hey, they all do it."

Q. They all provide that acne benefit?

A. They all provide that acne kind of prevention.

Q. Okay.

A. So if that answers your question...

Q. I think we're on the same page on that.

I guess -- let me just ask it --

A. But you asked two questions.

Q. Yeah. So let me follow up on that with Cenestin. Okay?

Are you aware, in anything that you've read as an expert witness in this case or outside, where doctors have assumed that Cenestin has the class effect for osteoporosis?

A. Absolutely.

Q. What is that?

A. The market research.

The market research that was done by Wyeth showed that doctors and even pharmacists perceive this effect, because it's got the same -- even though it's not considered a "bioequivalent" product, it does have the same molecules in it.

Q. Let me make sure I understand what you're saying.

The "market research" that you're referring to, that's market research that was done by Wyeth?

A. Yes, sir.

Q. And do you know whether in that market research -- whether there was an assumption that the product was, in fact, approved with an osteoporosis indication?

A. I don't know that indications were mentioned in the market research at all.

Q. Do you know whether or not in the market research the physicians or pharmacists are simply told that this is another conjugated estrogen; and they are not told, one way or another, about whether the FDA has come out and affirmatively stated, "This product is not approved for long-term use. This product is not approved for osteo"?

A. I do not know whether that kind of disclaimer was put into the research.

Q. You're aware, are you not, that the FDA has affirmatively stated that Cenestin cannot be promoted for long-term use, like osteoporosis?

A. Repeat the question.

Q. You're familiar that the FDA has come out with a directive that Cenestin cannot be promoted

for long-term use for treatment of things like osteoporosis?

A. I believe that I have read something about that.

Q. Okay.

A. Yes.

Q. And so it's not just simply a situation where Cenestin doesn't have the indication.

The FDA actually has a document that affirmatively states that the product cannot be promoted and is not approved for long-term use for osteoporosis; right?

A. I believe that -- yes.

Q. All right.

A. I believe you're correct.

Q. And would you agree with me that having something like that out in the marketplace is more likely to prevent managed-care organizations from assuming a class effect, than a situation where it's simply silent -- in terms of whether or not there is a class effect for a product?

A. I guess I don't understand the question

completely.
If -- you're asking me if they would turn the product down -- managed care, that is, would turn the product down for formulary inclusion because of lack of an osteoporosis indication?
Q. No. Let me ask it -- I'm trying to just address the particular point here, the class effect; okay?
Your example with Wyeth's contraceptives -- okay -- there wasn't an FDA document that came out and said, "This product is not approved" -- "affirmatively not approved for prevention of acne. This product cannot be promoted for the use of acne." It's simply silent; right?
Whereas, with Cenestin, the FDA has out and out -- gone out and affirmatively stated that the product is not approved for osteoporosis and not approved for long-term use.
And I'm wondering whether, in your view, that difference could impact whether or not managed care would assume a class effect.
A. I will tell you that I doubt that there

would be any difference; and I'll tell you why: Because I don't see those letters affirmatively going from the FDA directly to physicians or other people in the industry.
I see them potentially being brought by Wyeth-Ayerst, which easily could have been done by Johnson & Johnson for anyone else that went out to promote their product for an acne indication.
So if you're asking me: What's the impact of that specific event, of the FDA saying -- you know, even if it's in a press release, I doubt that there's a lot of physicians that look at the press releases and things like that.
So, I don't know how I would --
Q. Fair enough.
Well, do you know, for example, whether or not Aetna looked at the FDA's determination that the product wasn't approved for long-term use in not putting it on formulary?
A. I don't know that for a fact.
I do know that there were some companies that mentioned that to the managed-care

sales group at Viking.
Q. Do you know whether or not the Blue Cross and Blue Shield of California -- or, I'm sorry, Blue Shield of California -- again, this is an example -- on its own reviewed the medical literature, reviewed the FDA information, and concluded that they could not simply conclude that there was a class effect, in light of the FDA's affirmative statement that the product is not approved for long-term use for osteoporosis?
A. I've not seen anything specifically mentioning class effect -- either that, or it was something that I just totally glanced over when reviewing.
MR. DOBIE: Let me ask you about the documents that you did review, because I was curious about that.
Could you mark that as the next exhibit.
(Defendant's Exhibit Number 1078 was marked for identification.)
BY MR. DOBIE:

Q. Exhibit 1078.
Mr. Simon, we've given you Exhibit 1078. This contains a list of the documents, it says were provided to Paul Simon.
A. Um-hum.
Q. Do you know how these documents were selected to provide to you?
A. I asked for marketing materials -- which was specifically what my directions were, to be the marketing expert -- and to have those sent to me, which I believe was done.
Also, contracts were sent to me.
Q. Did you ask to review any depositions of employees from Duramed?
A. I did get some field communications.
I did get -- I did -- I'm trying to think if I requested specific -- the only thing I requested specifically was everything that would be included in Dr. Kolassa's arguments or on his deposition or report.
Q. But this is the list of documents that you reviewed; right?

A. Well, there's a lot of documents there. I can only assume that this is the list.
Q. Well, it doesn't appear that you reviewed any depositions of anybody from Duramed; is that correct?
A. From Duramed?
Q. Yes, sir.
A. No.
Q. And it doesn't appear that you reviewed any depositions of anybody from Wyeth; right?
A. Wyeth, individually? No.
Dr. Kolassa? Yes.
Q. So the only deposition that you've read in this case that you're basing your opinion on is the deposition of Dr. Kolassa and Mike Williamson, who worked for Solvay; correct?
A. I did get Mike Williamson's, by the way.
Q. That's what I said.
A. Yeah.
Q. So those are the only two depositions that you're basing your opinion on?
A. Complete depositions, yes.

There were little snippets of things, obviously, that were included in some of Dr. Kolassa's things.
I did get communications -- you know, field communications, which I had requested. There are field communications in here.
But in terms of depositions, no.
Q. Sir, are you familiar with the medical literature that speaks to evidence-based medicine?
A. Only as a result of having read Dr. Kolassa's report.
Q. You didn't read Dr. Schondelmeyer's deposition or report?
A. No.
Q. Do you disagree with Dr. Schondelmeyer, that evidence-based medicine should be the method that's utilized by doctors and managed-care organizations in determining what products should be prescribed?
A. Without knowing that much about evidence-based medicine, I'd have a difficult time answering that question. So...

Q. You're not disagreeing with the notion that doctors and managed-care organizations that are involved in trying to make a decision of what product they should either provide on a formulary or prescribe to the patient directly should make use of the medical literature and the evidence that's out there in the literature supporting a particular product; right?
A. Am I saying that they shouldn't look at that? Absolutely not. I think they should look at that.
Q. All right. And would you agree with me that in 1999, when Cenestin was launched, and in 2000, when as you put it before they really got up and running -- that the evidence supporting Premarin -- the medical literature that was out there, the studies -- that that was -- and even patients' and doctors' experience with the product -- that was a distinct advantage that Premarin had over Cenestin?
A. Would I say that it would be valuable to have 3,000 studies, as they were promoting it?

Q. Yes.
A. You're asking me an interesting question, especially in light of what's going on today.
I think it would be absolutely great for every product to come out to have that; but as you know in the case of products that are launched, I don't know of anybody that comes out with 3,000 studies.
So I don't know how to assess what's the value of having that wealth of data. I don't know.
Would it be valuable? Sure.
Would it be something that would maybe say I'd get 45 percent marketshare instead of 50 percent marketshare? I don't know. I honestly don't know.
Q. Price -- this is page 6 of your report.
A. Um-hum.
Q. The heading says: "Price was not the issue."
Let me ask you first: Are you aware of any witness from a managed-care organization or

within Duramed, within Cardinal, within Solvay, that has testified that they believe that the price of this product was appropriate?

A. I am aware that the -- that an individual from NPA made a comment to that effect.

Q. That the price was not appropriate?

A. That the price was too high.

Q. Are you aware of others that thought the price was too high?

A. I can't speak to who, no.

Q. Were you aware, for example, when you wrote this report that the head of managed care for Duramed believed that the price of the product was too high?

A. I was aware that there were people out there that looked like -- or that expressed a concern that the price might be too high.

Q. Were you aware that the person, Mr. Neeley, who was responsible for calling on managed care -- Mr. Neeley was with Viking, and Viking was the organization responsible for calling on managed-care companies -- that he too believed

that the price was too high?

A. I don't know if it was Mr. Neeley's report that I read or not, but I did read a report from an individual expressing a desire for them not to do a price increase.

And all I can say is: That's real typical for a sales individual to make that kind of comment, because they have to go out and sell products.

The issue, I guess, that I'm having a problem with is that when it comes to putting a product onto a managed-care formulary, the price that's presented to the marketplace as an AWP is of absolutely no relevance -- or maybe I shouldn't say "of no relevance," but it is of little relevance, in my experience.

Q. What is the experience that you have that you're drawing on to reach that conclusion?

A. Having done one thing: The project for Prilosec.

And the other is calling on managed-care customers while I was at Teva.

Q. So that's calling on managed care at Teva, which was a generic company?

A. Um-hum.

Q. And Prilosec, where you were asked to do a study of the impact that generics would have on Prilosec's marketshare once the generics came on line?

A. (Witness nods head.)

Q. What is it about the Prilosec experience that leads you to believe that the price was irrelevant?

A. First off, it's not just -- you know, I can't just say that nothing else that I did over my history is relevant.

I've been in the business for a long time, and it isn't just being drawn from these projects. The Prilosec project is the most recent one.

But quite frankly, I have been talking to these people. I know several of these individuals for a long time, including the time that I was at Teva, and actually did call on them.

And the issue of price -- they're public companies. They need to make money. They're looking at: What are the rebates going to generate for me?

And I think any of the companies that you talk to, any of the PBMs or people that are involved in these formulary decisions, are going to tell you that the cost is the last thing that they look at.

Q. So the product attribute is the first thing?

A. The product itself -- I mean, they will look at that. You know, what is it?

Now, the reality of it is that, yes, indeed, they will look at what the rebates look like and eventually what it is going to end up in the marketplace.

Q. So eventually they look at rebates and price; right?

A. I think -- yes.

Q. And are you aware that there are numerous managed-care organizations that repeatedly informed

Duramed that deep discounts on Cenestin were necessary because there was no demand for the product?

A. No, I'm not aware of that.

I don't know what one has to do with the other.

Q. Are you aware of --

A. Are you saying that they required deep discounts because there was no demand? I did not see that.

Q. Well, one strategy -- right? -- to launch a product -- and we're talking about Celexa, I think -- have we talked about Celexa?

A. No; but you can talk about them.

Q. Okay. Celexa is a product that competed with Prozac?

A. Um-hum.

Q. And it was manufactured by whom; do you know?

A. Prozac? Eli Lilly.

Q. No; Celexa.

A. Forrest.

Q. Forrest.

And did you have any involvement in Celexa --

A. No.

Q. -- when you were consulting with Forrest?

Do you know that the strategy for Celexa was to launch at a big discount to Prozac?

A. I'm aware that there have been products brought to market that way, yes.

Q. And are you aware that physicians would prescribe Celexa for the cash -- their cash patients?

A. No, I'm not aware of that.

Q. Are you aware of any of the literature that suggests that doctors prescribe different products for patients that are, let's say, in the Medicaid class versus the insured class?

A. That is totally contrary to what I understand.

Q. So you haven't seen literature to that regard?

A. No, I have not.

Q. Have you seen literature to the effect that doctors prescribe different products for cash-paying customers versus insured customers?

A. Tell me what you mean by "different products."

Q. Different pharmaceutical products within a particular class, depending upon whether they're insured or if they're cash-paying customers.

A. I am sure -- and if you look at some of the research, you'll see this as well -- some of the doctors in the Wyeth research made comments to the effect that that's why I write "medically necessary," etc. -- so that they aren't substituted at the drugstore.

But I am absolutely certain that there are doctors that will do different prescribing habits and provide generics or something like that to someone who is an elderly cash-pay patient.

If that's where you're going, I do know that there are examples of that, yes.

Q. You have seen the data that suggests --

A. I have not seen the data. I'm speaking,

experience.

Q. I see.

Well, are you aware of -- in this case -- of managed-care organizations suggesting that what Duramed should have done was price the product at a deep discount, build up demand within the cash-paying part of the market and Medicaid/Medicare, and then once you have demand that they would consider the product on formulary?

A. You're losing me again.

Are you saying that Wyeth would propose that?

Q. No; that managed care organizations suggested that to Duramed.

A. I'm not aware that managed care had suggested that, no.

And -- well...

Q. Would you agree that an increase in rebates would result in a lower net price paid by managed-care organizations for Premarin?

MR. PARKER: I just didn't hear the question. Could you read it back?

MR. DOBIE: Yeah.
Q. Would you agree that larger rebates would, in turn, result in a lower net price for Premarin for managed-care organizations that were reimbursing for the product?
A. It's a difficult question to answer, and I'll tell you why. I'll elaborate.
Managed-care companies are in the business of doing several things -- one of which is to get rebates and to share those rebates, sometimes, with their customers, the employers.
So will it actually reduce the price or the cost or the net cost, if you will, to managed care? I think it would be infinitesimally different.
The answer to your question is: Obviously, if you buy something or you're going to get someone to give you $10 every time somebody does something for you, and the money that's paid is to put the product on the formulary -- then, yes, I would have to say perhaps you're correct.
But it's really tough -- it's tough

for me to assess it. It's a complex question.
MR. DOBIE: Okay.
Let's take a two-minute break, if we could.
VIDEOGRAPHER: The time is 12:08.
We're off the record.
(A recess was taken.)
VIDEOGRAPHER: The time is 12:16.
We're back on the record.
BY MR. DOBIE:
Q. Sir, can I refer you to page 7 of your report, the Roman numeral IV: "Cenestin did not have equal access to 60-70% of managed care lives."
A. Correct.
Q. Now, you say here that you don't -- you've reviewed and seen documents that indicate that Cenestin had access to 60 to 70 percent of the managed-care lives; right?
A. Yes. I've seen documents where people have claimed that they had that.
Q. And the people that have claimed that -- it's not Wyeth, it's Duramed; right?

A. Right.
Q. And you want to say, "I don't know for certain why Duramed or Viking contained these figures"; right?
A. Um-hum.
Q. But then you go on, and you look at the Novartis report and you look at some other documents from Solvay and Wyeth; right?
A. Well, and I also looked at other documents from Viking, which also represent the same -- basically the same numbers -- that, no, in fact, they didn't have access to 60 to 70 percent.
It's like the people from Viking were saying, "Yes, we do"; and then they were saying, "Oh, no, we don't. Here is what it is."
Q. Let's look at some of those documents and see whether or not we can get any clarification here.
First, let me show you what has been marked as Exhibit 301.
These are already marked. So we're all set there.

For the record, Exhibit 301 is a copy of a memo from Mr. Carter, who is the head of managed care at Duramed, to Barb Casey, at Solvay -- referencing, I guess, a planned meeting with Jeff Arington, the president of Duramed; Bill Palmer, John Neeley, and Bill Grunick from Viking.
Have you ever seen this document before, sir?
A. I don't remember seeing this. Is it in my documents?
Q. In your list?
A. Yeah.
I don't see it there.
Q. No. No; I don't see it either.
A. No, I haven't seen it.
Q. It's a breakdown, is it not?
In Exhibit 301 there is a breakdown of HMO, formulary breakdown. And then there is a breakdown of various MCOs and PBMs and their formulary status; right?
A. Um-hum.
Q. And if you look at the page DUR10964 --

A. Okay.
Q. -- there is a list of HMO formularies, and there are totals at the bottom.
And the totals say that within HMOs 65 percent of the lives are in an open formulary, 11 percent of the lives are in three tier, and 24 percent are in closed formularies.
Do you see that?
A. Yes, I do.
Q. Do you have any information that any of the HMOs that are listed in Exhibit 301 for which Duramed has in its own documents that the formulary status is open or three tier or closed -- do you have any information that any of these are wrong or incorrect?
A. Specifically?
I can tell you what I think; but I cannot give you information that I know, specifically, that these are closed.
Q. Well, I mean, I'm not asking you to guess.
A. Anything I would say -- for example, "John Deere," that was not my understanding that they were

open.
Other than that, no, I cannot -- this could be true.
Q. In fact, "John Deere," sir, was a situation where Cenestin was on formulary?
You didn't know that?
A. I did know that.
Q. Oh, you did know that. Okay.
A. But I didn't know it was an open formulary.
Q. So when you say in your report that you don't know why Duramed and Viking's contain these figures -- you don't have any information that any of these specific HMOs that are listed here, that they aren't open or three tier or closed, as indicated in this document?
A. I can tell you that when I look at this -- for example, where is PCS? It was on there.
Blue Cross/Blue Shield -- oh, using PCS as their PBM.
So I can't tell you. No.
Q. Now, let's look at the PBM page -- which

is the last page in the document, DUR10966.
All right. And here they have got -- they've gone through some of the PBMs -- "Advance PCS," "Caremark," and others.
They've got 62 percent of the lives being on open formularies, 30 percent three tier, and 8 percent closed; do you see that?
A. Yes, I do.
Q. Do you have any information that any of these PBMs that are listed here -- that this isn't the situation for Cenestin?
In other words, do you have any information to suggest that 62 percent of lives within PBMs are not on open formulary as it relates to Cenestin?
A. As it relates to Cenestin?
Now, you've -- you've thrown me. What do you mean?
Q. Here's what I mean:
The testimony from the witnesses is that these documents were prepared based upon information received by Duramed and Viking -- from

each of these managed-care organizations, as they were looking at the situation for Cenestin.
A. I can tell you that if you look at the first one, "Advance PCS" --
Q. Yes.
A. What does that mean? "MD"? The state?
So that means, within the state of Maryland they have 33 million lives -- in the state of Maryland, 33 million lives -- am I reading that right?
Q. I think that the -- the state category -- again, this isn't a Wyeth document. This isn't my document. This is a document from Duramed, who you're working for.
I don't know the significance of the state column. But we've got --
A. Well, I guess what I'm saying is that, you know, just looking at the very first number has got me concerned right away about the value of this -- of this report.
Q. But do you have any information -- all right -- that any of these -- whether it's Advance

PCS, where it says 75 percent of the lives are in open and 25 percent are in three tier for Cenestin -- that that's not correct?

A. I can tell you that 50 percent of Advance PCS's business is in programs that they have a preferred list, a preferred category -- which you'll see in the tables that I've presented.

50 percent of their book of business falls within that preferred category, where they actually call physicians, patients, and pharmacists for products that are not on formulary or on their preferred list.

This document, to me -- if I'm looking at it and I see someone telling me there's 33 million lives that PCS has in Maryland, I've -- it goes to the problem with -- I mean, they claim 65 million lives. Is half of it in Maryland?

Q. No.

Sir, I think all of these -- this is the -- where they believe that the -- that the -- Caremark is headquartered in Illinois; right?

Eckerd is headquartered in Florida.

Express Scripts/DPS, is headquartered in Missouri.

Do you see that?

A. Um-hum.

Q. And they've got 222 million lives. And we've got 62 percent are open, 30 percent three tier, 8 percent closed.

And what I'm asking you is: Do you have any information, that you've seen anywhere, that supports the idea that that isn't what the situation was for Cenestin?

A. Okay. So what --

Q. See, what you have said is that, generally speaking, Advance PCS is, you know, 50 percent in preferred or whatever.

I'm talking about for Cenestin, specifically.

Do you have any information that any of these that are listed here by Duramed as open, that these are wrong?

A. Do I have any information about these, individually or specifically, that they are wrong?

Q. Yes, sir.

A. I cannot say that any one of these particulars is wrong, because I don't have the information on the particulars.

Q. Right.

A. I can tell you that the "222 million" that they're totaling up to is wrong.

Q. It should be higher?

A. It should be much lower.

Q. Which of these do you think is lower?

A. Well, there are 240 million people in the United States that have health-care coverage; perhaps, 200 million that have a carve-out benefit for pharmaceuticals.

This exceeds that entire population.

Q. So there is some double counting?

A. I don't know if it's double counting or what it is.

Q. You're not familiar with the fact that some people -- if my wife, you know, works for the school system and she's got insurance -- and at my law firm, that we've got insurance -- that they'll

both be counted.

My plan might be through Aetna. Hers might be through Advance PCS.

And that's why you get more than 240 million Americans listed?

A. I'm familiar with -- in PPO situations, that's correct.

And you also have a situation where you may have a PBM and a mail order, and get counted twice.

You may have -- and this is part of the problem with the data: You have PPOs for chiropractic, for podiatry, for dentistry, for everything else -- all of which could be included in these numbers.

MR. DOBIE: You mentioned PCS. So let's just use that as an example.

Why don't we mark this as the next exhibit.

(Defendant's Exhibit Number 1079 was marked for identification.)

MR. PARKER: I'm sorry. Where are

we?

MR. DOBIE: 1079.

MR. PARKER: Okay.

BY MR. DOBIE:

Q. Mr. Simon, I've handed you what we've marked as Exhibit 1079.

And just as an example -- all right? -- you were talking about, at PCS, how you're familiar with, you know, how much of the business is typically in a preferred situation.

But look at that first paragraph.

Have you ever seen this Exhibit 1079 before?

A. Yes, I have.

Q. So you're familiar, then, that what Viking was reporting is that Cenestin would be available at the same co-pay level as products accepted for inclusion in the 2000 formulary programs in at least 90 percent of their book of business or over 45 million lives.

Do you see that?

A. Yes, I do.

Q. And so regardless of whether PCS's situation may have been on how they handle all their other products, are you aware that Viking called on PCS and PCS made the decision to reimburse Cenestin like Premarin, even though it wasn't on formulary for 90 percent of their book of business?

A. I am familiar with that.

Q. And there's other examples as well.

You've got -- with -- if you look at the next page, there's a discussion about "United Healthcare." That's a big HMO. 44 regional plans across the country.

Cenestin -- in the second paragraph, it states that Cenestin is considered non-formulary, however is being reimbursed in the majority of their plans at the $13 co-pay.

Do you see that?

A. Um-hum.

Q. And if you look at -- I don't know. I mean, we can go through these.

Strike that.

What I'm getting at, sir, is:

When you say that you don't know why Duramed's figures contain these figures of 60 to 70 percent -- all right, I understand you haven't read all the depositions -- or any of the depositions beyond Mr. Williamson's and Mr. Kolassa's -- but you don't have any information -- do you? -- that suggests that the numbers that are provided in Exhibit 301 are incorrect?

A. The data that I have provided from the audited -- from the audit sources -- this is not possible to be true, if the data that I have presented is true or the data that Wyeth has prepared in their research is true.

Q. Well, let me ask you about the data that you presented.

And you mentioned first the Novartis and the Wyeth information. So let's look at that.

A. "Novartis"?

And that's the very next page.

Q. Right.

You've got it summarized in your report. Okay?

A. It isn't the easiest thing to read, though.

Q. The Novartis data?

A. "Novartis"; right.

Q. "Novartis."

Okay. Looking at your table on page 8, this only relates to HMOs; right?

A. This only relates to HMOs.

Q. And HMOs are -- what? -- 30 percent of the insured marketplace in 2000?

A. No; they're bigger.

The difference between HMOs and PPOs is that PPOs get counted multiple times. HMOs represent something in the neighborhood of 100 -- now, I believe, it's like 110 million lives.

Q. At the time of the data that's here, 2000 HMO --

A. 100 million lives.

Q. You think that's 100 lives?

A. Yes.

Q. You think that the data, the 2000 HMO -- the data represents 100 million lives?

A. Correct.
Q. All right. Now, that Novartis study -- they don't actually go out and survey all of the HMOs, do they?
A. No.
Q. All right. They go out; and they survey a portion, a sample. Right?
A. They're an audit.
Just like IMS, they go out and use the same -- as a matter of fact, they use -- the audit source that this comes from used to be owned by IMS. So they apply the same kind of statistical routines to find out how many people they need to go talk to, to make it representative of the nation.
Q. All right. And the table that you've prepared here is a summary of the Novartis data; correct?
A. It actually comes directly from their report.
Q. And what you have listed here, just to sort of walk through -- you've got the co-payment design, whether it's a one tier or multiple tiers.

And then you've got it broken down into commercial group. I guess that's insured, Medicaid, Medicare, and overall.
Right?
A. Correct.
Q. Now, the Medicaid and Medicare portion of the chart -- let's just start with that.
No restrictions by Wyeth, no contracts that prevented Cenestin from competing in any way in the Medicaid or Medicare market; right?
A. Correct; except in the selective and partially selective categories -- in the partially selective category of business.
However, they're all one tier. So the fact is that, no, there was no detriment.
Q. So we're talking, really, about the commercial group, then.
A. Well, actually, we're talking about the overall.
Q. All right. So, you want to talk about the overall. That's fine.
A. Well, no. The point is: Medicare and

Medicaid do not represent -- and I didn't put on this chart, you know, who's responsible for what.
You're right. The commercial group would certainly be the biggest portion of their business.
But to really get the assessment of HMOs, the overall is the way to look.
That's what I look at.
Q. That's fine. If you want to look at overall, that's fine.
And what you've done is: You've said that the portion that's open within HMOs, you've combined the first and -- the one-tier and the two-tier formularies within the open group; right?
A. Correct.
Q. All right. And then in the three-tier, you're assuming -- right? -- if you look here, that 33 percent -- you're assuming that, within HMOs, Cenestin is not -- is not reimbursed in the second-tier category; right?
A. I'm not assuming anything about Cenestin in this report.

Q. Okay.
A. I'm just presenting: This is the marketplace as the marketplace exists in HMOs.
Q. All right. But what I'm interested in -- and that's fine -- you're not suggesting in this report, Mr. Simon, that if we were to look at the underlying data from Novartis and look at who are the HMOs that are reporting -- that even though they might have 33 percent of their lives in a three-tier formulary, that there wouldn't be HMOs within that that have put -- that are still reimbursing Cenestin in the second tier; right?
A. I'm sorry. I'm having difficulty following.
What I am saying is: This is what the marketplace looks like. It does not necessarily represent where Cenestin falls within this marketplace.
Q. Okay.
A. Is that your question?
Q. Yes. Yes. Okay.
And an example would be -- maybe, we

were just looking before at Aetna.

Aetna is -- where was it, here? We were looking at Exhibit 1079.

You know, 1079 says: At this time, while no contract exists with Aetna, Cenestin will not be included in their drug formulary.

So, again, it wouldn't be in the second tier; but for the majority of Aetna's plans, Cenestin will be covered and reimbursed at the standard co-pay level and not actively intervened against.

In other words --

A. That's what he's saying.

I don't know that.

Q. Right.

But this table that you've put together here, it's not -- you haven't attempted to bring in Cenestin, specifically, and whether it fits into the -- whatever fit in -- or where it would fit within the table?

A. That's correct.

Q. Now, on one of the other documents that

here that this data comes from currently tracking 276 regional HMO/PPO targets for Cenestin reimbursement status.

Do you see that?

A. Um-hum.

Q. Do you know who those 276 regional HMOs are?

A. No.

Q. All right. Do you have any reason -- I mean, so you're not in a position to say that -- or to know whether or not those 276 regional HMO/PPOs are any different -- are the same or different than the HMOs that are listed in Exhibit 301 that we were looking at before?

A. No, I don't.

Ask the question again. I'm not sure.

Q. Here's what I'm getting at:

These HMO/PPO targets, regional targets -- these could be things like, you know, the United Auto Workers, the American Airlines health plan. It could be things like that.

you mentioned, you talk about the documents that may have gone the other way, in terms of how much is open; and I want to show you some of those just to make sure we're on the same page there.

I hand you what we marked as Exhibit 16.

Okay. And for the record, Exhibit 16 is the "2000 Business Plan, Cenestin Tablets," July 2000, from Mike Williamson of Solvay.

Sir, this is one of the documents, I think, that's on your --

A. I've seen this.

Q. You've seen this one. All right.

And if you look at page DUR29313, this is the -- some of the data that you were talking about that had Cenestin's reimbursement status --

A. Yes.

Q. -- as being less than 60 to 70 percent --

A. Yes.

Q. -- as referenced by Dr. Kolassa?

Now, let me ask you this: It says

It might not be -- we don't know, looking at this data here, who these 276 regional HMOs are; correct?

A. I don't know who they are.

I've got to make an assumption that they are not going to be out chasing ether in a marketing plan. I mean, they're not going to put a plan together that says: I want my sales reps to go to these plans that don't matter.

So, yeah, I make that assumption that they're in the business to go out and sell the product.

Q. Well, do you know to what extent Solvay called on managed-care plans, as it relates to Cenestin?

A. No, I do not.

Q. Do you know whether or not they did at all?

A. I believed that I've read some places where they have indeed called on managed-care customers.

Q. As it relates to Cenestin?

A. Solvay.
Q. Solvay?
A. Yes.
Q. Okay.
A. But -- but I'm -- I'm -- I'm not sure.
Q. All right. And then on the next page, where it says "Corporate Targeted Accounts."
A. Correct.
Q. And again, do you know who those "Corporate Targeted Accounts" would be?
A. No.
You know, when you asked me that question about Solvay calling on managed-care accounts -- I don't see how they could avoid talking about Cenestin, when they're already in those offices talking about other products that they -- that they promote and they have their own managed-care department.
Q. You think the natural thing would have been to have Solvay call on managed care?
A. I think that Duramed did the right thing in bringing Viking in before they launched a product

to get them prepared to do it, because the agreement with Solvay never happened until -- what? -- October.
So there was no signed agreements until October. They couldn't rely on Solvay.
Q. Do you think that it would be appropriate to have had Solvay calling on managed care?
A. Do I think it would be appropriate? I think it would be something I'd want to investigate a year out, or so, after -- you know, when I was preparing my next marketing plan.
Would it be something that I would consider?
Q. Yes.
A. Yes, I would consider it.
Would I do it? It depends.
Q. Do you think that Cenestin might have been impacted by -- or received fewer formulary approvals if Solvay was only promoting its products for formulary inclusion, as opposed to Cenestin?
A. Let me see if I understand this correctly.
If you're asking me if I would award

Solvay the product to promote in managed care -- and then they never called on managed care for that product -- would it make a difference?
I don't know if that's your question or not; but if that is, then I think the answer is: Definitely, it would make a difference. Someone needs to call on managed care.
Q. Right.
And so in other words, if Solvay was only promoting its products, as opposed to Cenestin, when it called on managed care -- that could have hurt the uptake of Cenestin?
A. If they didn't have Viking calling on them?
Q. I want to back up.
You said a minute ago that you think it would have been natural for Solvay to have been promoting Cenestin --
A. No --
Q. -- to managed care.
A. -- that's not what I said.
What I said -- I hope I didn't say

that -- what I thought I said was:
It would have been natural for Solvay to hear about Cenestin while they're in there talking their other products.
If the managed-care company, whoever -- Aetna -- whoever -- if they're calling on them for another product that they're manufacturing at Solvay and -- it would be just natural, I would imagine, for the purchaser to say, "How is Cenestin going? Why aren't you guys selling it?"
I mean, I could see that come up.
Q. But you don't know that that happened?
A. But I absolutely do not know that that happened.
Q. In fact, it could just as well be likely that they were forbidden from talking about Cenestin when they went in?
A. It very well be that they were forbidden to talk about it.
That doesn't mean that you don't hear things.

A. But, yes.
Q. You don't know whether that happened, one way or the other?
A. Do not know that.
Q. And then on page 9 of your report, you talk about how Wyeth personnel report that Duramed's access to managed care has been restricted by Wyeth's contracts.
And you reference some documents at the bottom of the page that refer to Express Scripts and Medco.
So I assume you're familiar with the situations with both?
A. (Witness nods head.)
Q. You have to respond verbally.
A. Yes.
Q. All right. And you understand that the exclusive contract -- exclusive, sole, conjugated-estrogen contract with Express Scripts only related to the non-bid-grid portion of Express Scripts' business?

Q. Did you know that?
A. I was not aware that there was a significant difference between the two.
Q. Do you know whether or not, within that portion of the business, it's almost 100 percent open formulary?
A. And how much -- well --
Q. Within the --
A. No, I didn't know.
Q. How about with Medco; do you know what percentage --
A. Now, wait. We're talking -- you were talking Express Scripts.
Q. Yeah. Now let's switch to Medco. Let's talk about Medco for a little bit.
A. Wait. Let's stay on Express Scripts, because my understanding was that they had a bid-grid contract with MedImpact.
Is that what you were referring to?
Q. No. I was talking about Express Scripts.
A. I'm talking Express Scripts too.

A. But there was a process that they went through, that -- this "bid-grid" thing that you're talking about -- where Cenestin was put on, but that it was subsequently removed as a result of discussions with Sally Miller or -- am I on target?
Q. That's it. That's the Express Scripts 1999 bidding for the 2000 formulary bid grid.
A. So my answer to that is: Yes, I am familiar with that.
Q. And you also know that on the bid-grid side that Cenestin went on formulary in 2001; right?
A. I didn't review 2001, no.
Q. How about at Medco; do you know, within the estrogen category, how open the Medco plans are?
A. In the ERT category, no, I do not.
Q. So it could very well be that, although Wyeth and Medco contracted, that Wyeth would be the sole conjugated estrogen -- that, within Medco, Cenestin would be reimbursed at the same co-pay -- assuming it's, let's say, 90 percent open?
A. Say that again, because I am -- this is not my understanding that they're anywhere near 90

percent open, especially with their mail-order business.
Q. They didn't provide you with the documents relating to the --
A. They may have, but it may have been detail that I did not get.
Q. Mr. Simon, then, you're not familiar with what portion of Medco lives are in an open-formulary situation?
A. That's correct. I am not familiar with how many are in an open situation.
Q. So you're not able to say, with Medco, to what extent Cenestin -- you're not able, then, to say, within the Medco lives, to what extent Cenestin was disadvantaged?
A. Within the Medco lives, no, I can't say if it's 1 percent or 100 percent.
Q. Now, let's talk about Medi-Span.
On page 9 of your report, you say that restrictions on 30 to 40 percent of the market is sufficient to seriously affect Cenestin's sales.
Let me start off first with that.

You note that if Cenestin was excluded from 30 to 40 percent of managed-care lives, that this could still sufficiently be restrictive -- to result in decreased Cenestin prescriptions by physicians.

I want to ask you first about the "if."

You're assuming, for purposes of the report, that that might be the number; but you don't know?

A. I'm -- I'm saying that, even if you're correct or even if Dr. Kolassa -- or whatever the number is -- 60 to 70 percent of lives were open, this still would be a difficult situation.

Q. What if it was 60 percent open and then another 30 percent in three tier -- like what we were looking at -- I think it was 24 percent, three tier, as indicated in Exhibit 301 -- but in fact, the product, because Cenestin has a low cash price, was being reimbursed in second tier?

A. I did not evaluate the impact.

Q. Now, tell me about Medi-Span.

And you mention that you were out there talking to doctors and trying to determine to what extent a computerized formulary software package might be something attractive to physicians.

And you told me that it was something that ultimately wasn't marketed. The company was sold.

When you talked to physicians, did you do a statistical analysis, anything like that?

A. No. No, sir.

Q. What was the number of physicians that you talked to about the computerized formulary software?

A. Oh -- I can't remember. It's certainly going to be less than 24 and more than 12.

Q. Okay.

A. Now, that's physicians.

Q. Yes.

And then, how do you generalize from a sample that small?

A. When you get the same answer from everybody, it's pretty -- pretty conclusive that that's what's happening.

Besides that, there are other individuals that you talk to to find out their interest in the product as well.

And that would be the software companies that are providing physician practice-management software, the fact that they would talk to their physicians and get that input and give that same input to you.

Q. And what you're saying is that, based upon talking to somewhere between 12 and 24 physicians, you can say that for a drug to be disadvantaged by a third of the doctor's managed-care patient load is a significant disadvantage?

A. I'm saying that, based on the things that are in here and that I was told --

Q. Right.

A. -- by those individuals, it would definitely be detrimental to the product.

Q. But you're not saying that a product couldn't succeed -- products like Lescol and others that have succeeded without a formulary placement -- right?

You're not disputing that?

A. I'm not saying that a product can't succeed, like a Celebrex -- which was on prior authorization.

But I'm also -- when you're talking about a Celebrex, you're not talking about a product like this. You're talking about a brand-new category, etc.

Yes; you're right.

MR. DOBIE: Let's take a -- see if that lunch is -- they might have just stuck it next door -- because I'm kind of hot in here too, I'll be honest with you.

VIDEOGRAPHER: The time is 12:55. We're off the record.

(Whereupon, at 12:55 p.m., a lunch recess was taken.)

AFTERNOON SESSION

(1:24 p.m.)

VIDEOGRAPHER: The time is 1:24.

We're back on the record.

BY MR. DOBIE:

Q. Mr. Simon, I wanted to visit with you about the section of your report that's Roman numeral V, Duramed's marketing program.

And you say that the -- do you have it, page 11 -- that the original market plan that was prepared by Duramed in 1998 is what would be expected from a small manufacturing company.

And there is a -- you know, a few places where you reference the fact that the marketing program was about what you'd expect for a smaller company.

I'm just wondering what you meant by that.

A. Well, when you market a product, you -- there are going be certain things you're going to do:

You're going to go to the market.

You're going to do your market research. You're going to talk to your customers and find out what kinds of things were important to them.

Then you're going to try and develop a strategy, and have a lot of meetings internally and put together an appropriate message, based on the strategy, and go to the market with that message.

You're also going to look at what kind of sales force you need in order to reach that market.

All of the things that are required to bring the product to the marketplace they did.

Now, if I were launching a product like Cenestin -- and I know I probably shouldn't be getting into Cenestin -- but when you're marketing big, big products you have big, big budgets. And you would probably do a lot more research and things like that.

Q. Well, do you think if you're trying to -- I understand it's a small company.

But if you're trying to have a big

product -- a product with $100 million in sales rather than, let's say, 10- or 20-million dollars in sales -- don't you think you need to undertake the promotion like the bigger companies?

A. I think if you're looking to achieve a 6 percent share of the marketplace that's available to a product, you are looking to do things that you wouldn't normally do if you were looking to come out with something that was a ground-breaking or earth-shattering kind of a product.

If you're going into a class like -- like this and looking for a 6 percent marketshare, I think that they did plenty -- sufficient.

Q. Well, when you're talking about a 6 percent marketshare in a product that the entire category is, let's say, $100 million -- that's one thing.

But this one, a 6 percent marketshare -- they were looking for $100 million in sales; right?

A. Um-hum. Um-hum.

Q. And don't you think that you need to

spend, you know -- or don't you think most companies, to achieve $100 million in sales, just in their first year, that they would --

A. I don't think that's what it said.

Q. You didn't see the projections that they made?

A. The projections that I saw?

Q. Yes, sir.

What projections did you see?

A. I was under the impression that Mr. Arington had presented to Wall Street and others that, at the end of 18 months -- and I believe that's what was in Dr. Kolassa's report -- they would be at $1 million pace.

Q. Or $150 million pace; right?

A. 100- to 150-, maybe.

But the $100 million pace is what I was led to believe.

Q. And do you think that most companies, to get to a $100 million a year pace, would have to spend -- on promoting the product, on marketing the product -- $100 million in that first year?

A. Absolutely not.
And I don't think that you would find a major company that would even launch a blockbuster at that level.
Q. You're not aware of anything in the literature, anything within your experience that would suggest that you would need to spend that kind of money in order to get those sales?
A. That I would need to spend 100- to 150-million dollars?
Q. Yes, sir.
A. In order to get $100 million?
Q. Yes.
A. No.
Q. So where Dr. Kolassa says that the rule of thumb in pharmaceutical marketing, that a company would expect to spend 100 to a 150 percent of expected first-year annual sales on promotion -- is certainly not a rule of thumb in any of the companies where you worked?
A. That's correct.
Q. And not only wasn't it a rule of the thumb

in the companies where you worked, but you're not aware of that being true in the industry, generally?
A. I am not aware of that being true in the industry.
Q. And did you do any research to look and see whether or not Dr. Kolassa was --
A. In fact, I did.
I went back and looked at the -- some of the documents that he prepared or used in his documentation.
And the information that I got was that companies, for launching of a blockbuster, might spend -- and a "blockbuster" here means billion dollars plus -- they would perhaps spend 500 million in the five years leading up to and including that first year.
Now, that doesn't equate to 100 percent.
Q. What are you referring to?
What documents are you referring to?
A. I believe it's in the document about launching a blockbuster.

I do not remember what the numbers or anything like that are, but I believe it's in that document.
Q. Now, you have been tendered by Duramed as an expert in pharmaceutical marketing.
You understand that?
A. Correct.
Q. And you understand that Duramed also has another expert by the name of "Steven Schondelmeyer," and he has also given an expert opinion on marketing issues?
A. I'm aware that Steven Schondelmeyer is involved. I don't know what his -- you know, what he has been requested to do.
Q. You've never reviewed his report?
A. No, I have not.
MR. DOBIE: Why don't we mark this as the next exhibit.
(Defendant's Exhibit Number 1080 was marked for identification.)
MR. DOBIE: For the record, Exhibit 1080 is a copy of a document from the U.S.

Congress, Office of Technology Assessment, "Pharmaceutical R&D: Costs, Risks, and Rewards."
BY MR. DOBIE:
Q. Have you ever seen this document before, sir?
A. I don't think so.
Q. Well, look at page "v."
That's the fifth page in.
A. Okay.
Q. There is like a "v" there.
And there is a list of principal contractors. And you see "Steven Schondelmeyer" is listed as one of the principal contractors, over on the top of the right-hand side?
A. Yes, I do.
Q. All right. Let me ask you to turn to page 90.
It says: "Pharmaceutical R&D: Costs, Risks and Rewards."
A. Okay.
Q. And in the column that is on the left-hand

side, it says: "Cost of Manufacturing, Marketing, and Distributing NCES."

Do you see that?

A. Um-hum. Yes, I do.

Q. And that has to do with new --

A. -- chemical entities.

Q. -- new chemical entities. All right.

And if you look down here, it says:

The office of technology assessment -- this is in the paragraph at the bottom of the line, the bottom of the page -- estimated manufacturing, distribution, marketing, and administrative costs from a variety of sources, including the existing literature and annual reports of six U.S. companies, with pharmaceutical sales comprising at least 65 percent of total company sales.

Do you see that?

A. Yes, I do.

Q. And it says in the next paragraph:

Marketing costs were assumed to be higher in the early years of product life and low

after patent expiration; but over the lifetime of the product, they averaged 22.5 percent of total sales.

Right?

A. That's what it says.

Q. And look at the next page, if you would.

There's a table that has the cost assumptions in the office -- the government's Office of Technology Assessment's analysis of returns on R&D.

And if you go down four lines -- one, two, three, four -- marketing costs is a percentage of sales.

Do you see that?

A. Oh, up here?

Yes.

Q. It's in the table.

A. Yes.

Q. And Year "1" --

A. Um-hum.

Q. -- it says "100.0% of sales"; doesn't it?

A. That's what it says.

Q. And for Year 2, "50.0% of sales"?

A. That's what it says.

Q. So you'd agree with me that at least the U.S. Government has concluded that, on average, pharmaceutical companies were spending 150 percent of their sales on marketing during the first, at least, two years of the launch of the product?

A. No, I don't agree.

I agree that, for the six firms that they looked at -- which were Merck, Eli Lilly, Syntex, Schering-Plough, Upjohn, and Pfizer -- that that may be the truth.

Q. Okay.

A. And I can assure you that that would be based on the type of product and the duration of their patents for these products, as well.

Q. But your statement in your report that there is -- that you're not aware of anything -- anything -- that one would expect to spend 100 to 150 percent of expected first-year annual sales on promotion -- when you wrote this, sir, you weren't aware of the government's report; right?

A. I was not aware of this report; and I still -- I still would want to look a lot more detail of this and what type of drugs they're talking about, because I know that it costs almost $800 million -- or at least that is what the Pharmaceutical Manufacturing Association says -- to bring a product to market.

Well, if I'm going to invest $800 million in a product that's going to come to market, I'm going to be launching a product that has blockbuster potential and I'm going to invest very, very heavily in it.

This product, they were looking at a 6 percent marketshare in a market that was -- has been around.

Q. So your view is, is -- if you're looking for only a 6 percent marketshare, that you don't need to spend money that would approach these figures?

A. I'm saying that, if you are looking to achieve a 6 percent marketshare, you're not going to spend the same money as you would trying to achieve

a 50 percent marketshare.
Q. Well, let me ask you this --
A. Does that make sense?
Q. -- can you name for me one $100 million product that was launched without spending at least -- I'm sorry -- one -- strike the question.
Can you name for me one product that got $100 million worth of sales in its first year, that was launched without spending $100 million in marketing?
A. Absolutely can not.
And by the way, this product wasn't looking to do 100 million in its first year.
Q. Well, in 18 months, can you name one product that was going to do 100 to $150 million in sales in 18 months that didn't spend 100- or 150-million dollars in marketing?
A. No, I can't.
You mean, branded products, now -- I'm assuming?
Q. Any product. Any pharmaceutical product.
A. I would have to think about this, but

there's a couple of products that come to mind that could have approached that.
Q. What are those products?
A. Clonazepam, for one -- which was a generic launched by itself.
Marketing, probably -- marketing costs at 1 or 2 percent.
Q. Right. So a generic, you don't have to market. That gets automatically switched.
A. I agree.
Q. Okay.
A. But that's why I asked you the question.
Q. I understand.
So with a branded -- the way you were trying to get me to revise the question is correct.
You can't think of any branded pharmaceutical product that got 100- or 150-million dollars in sales without spending 100- to 150-million dollars on marketing?
A. Off the top of my head, I cannot.
Q. Now, are you by any chance a member of the Pharmaceutical Marketing Congress?

A. No.
Q. Have you ever attended meetings of the Pharmaceutical Marketing Congress?
A. I may have attended one.
Q. When was that?
A. And I can't -- back in the mid-'90s, early '90s.
Q. What is "share of voice" in the pharmaceutical industry?
What does that mean, "share of voice"?
From a pharmaceutical marketing standpoint, what does that mean: "share of voice"?
A. Well, "share of voice" is looking at all the things that are going -- all the promotion that's going out to the physicians' audience and looking at your competitors.
And there's two ways of looking at it: There's share of voice, and then there's relative.
And what you're looking at is: Of all the promotional messages and dollars being spent

to provide messages to the audience, what is your share -- or what percentage of all of that message is coming from your product?
A long-winded answer.
Q. Well, does that include, for example, detailing physicians?
A. That would include detailing.
Q. How about direct-to-consumer advertising?
A. That would include that.
It would include journal advertisements.
Q. Okay. Now --
A. And depending on what kind of company you are, it could include other things -- because you can look at this differently for different companies.
Q. Now, you mention that you might spend less money if all you wanted was a 6 percent marketshare.
Let me ask you this: Do you know what Duramed's share of voice was in 1999, 2000, or 2001?
A. I saw the statistics. I don't know them

off the top of my head.
Q. About 8 percent or so, at the high end?
A. If that's what you say.
I -- I honestly don't remember.
Q. Would you agree with me that there is a correlation between the share of voice and how a product will do, a branded pharmaceutical product will do?
A. I would love to say yes, because it's an easy answer.
But the answer is: If you're giving a message that's bad, the answer is no. If you're giving a message that has meaning to it, that doctors perceive as being valuable, then the answer is yes.
If your competition is not giving the same quality of call, let's say -- if you're giving details in the first position which may come in, in terms of share of voice, at the same cost as a Detail No. 2 or 3 -- I guess what I'm trying to say is: You can't go, based on a -- one global number -- and say, "This is going to make the

difference," because that just isn't the case.
If you have a cure for AIDS, guess how much you would have to put in the marketplace to sell it? You wouldn't need any share of voice.
And that's -- believe me, I mean, that's really an extreme example. But, hopefully, I'm getting across what I mean.
Q. Are you aware of any product that has ever obtained, let's say, 10 percent of the marketplace without having a 30 percent share of the voice?
A. I haven't investigated that.
Q. Okay.
A. And I'm assuming, again, you're talking brands?
Q. Yes.
Okay. How about, have you ever looked to see whether or not you would have to have some percentage of share of voice to obtain what you said: 6 percent of the marketplace?
A. Here again -- I mean, IMS goes out and they make presentations every year.
And they give -- they give these

numbers, share of voice. And they talk about what's going on and how the product has managed to get from one place to another over time.
It really depends on the kind of product, the kind of marketplace that you're in, the kind of market -- you know, your competition -- all those things.
MR. DOBIE: Why don't we mark this as the next exhibit.
You mentioned "IMS." Let me show you a document.
What are we on? 10 -- 1081.
(Defendant's Exhibit Number 1081 was marked for identification.)
MR. DOBIE: For the record, Exhibit 1081 is a copy of a document produced by IMS on October 6, 2002, and presented at the Pharmaceutical Congress meeting.
BY MR. DOBIE:
Q. And, sir, have you ever seen this document before?
A. This, no.

Q. Have you heard of the publication of this information within the pharmaceutical marketing community?
A. This specific?
Q. Yes, this study that they did.
A. No; I'm not aware of this.
Q. So there was a 600-person congress of the Pharmaceutical Marketing Congress, where this was announced --
A. No. This was just presented five days ago.
Q. All right.
The IMS, as you mentioned before, they collect data on every -- on pharmaceutical products and every prescription that's written; right?
A. No. They collect a sample the same way the data was prepared for the Novartis audit.
They have a sample of data that they capture prescription information on.
They do sell information that captures the sale, the actual transfer of product --

Q. Right.
A. -- from one place to the next. But they don't capture every prescription.
Q. Every sale.
Now, the study revealed that throughout the 1990s no product has ever achieved at least 5 percent of sales without a 20 percent share of voice. Not one.
A. It's never -- say that again.
Q. No pharmaceutical product has ever achieved even a 5 percent share of market without 20 percent of the share of voice.
A. Share of voice; okay.
MR. PARKER: Where are you in the report?
MR. DOBIE: Look at -- look at page 18.
Q. So if you look at page 18 --
A. I'm getting there.
Sorry. I'm slow, but sure.
All right. I'm on 18.
Q. And if you look, you can see that they've

got Year 1 prescription share.
And then you've got Year 1 professional promotion share of voice.
And you can see here that nobody is over a 5 percent marketshare unless their share of voice exceeds 20 percent; right?
A. That's what they're showing.
Q. And --
A. But out of curiosity or maybe -- maybe -- I don't know if this needs to be reiterated now.
A 5 percent share over -- at the end of one year of sale is not the same as a 5 percent share going into the next year.
A 5 percent share, starting at zero, perhaps means you've got a 10-, 12-, 15 percent share that -- on Month 12 of that product.
So, I mean, this may well be true. But it's not -- we're comparing apples and oranges.
Q. Well, here's what I'm getting at:
All right?
If Cenestin's share of voice was 8 percent --

A. Okay.
Q. -- or less, depending on the year -- okay -- isn't it true that its sales are about what one would expect?
Wouldn't you agree with that, based on this data?
A. No, not at all.
Q. With all of the problems with this product, with its indications, with everything that we've talked about, and with the share of voice being below everybody else in the -- strike that.
Why do you think that Cenestin would be so much better than every other pharmaceutical product that has been launched in the last 12 years -- that their sales would have been 6 percent, when its share of voice was 8 percent and the money that it spent on promotions was a fraction of what is typically spent according to the U.S. Government?
A. I think that you are making some real interesting assumptions.
First off, when I look at this data, this is saying: At the end of a year, this is what

their share of sales are --
Q. Right.
A. -- which, like I said, may be -- I don't know. It could be that they are at a 20 percent share at Month 12, in order to accomplish this sale during the year -- because they start at zero.
Q. Well, look at the next page. Okay.
A. Well, I looked at -- frankly, I looked at some of the earlier pages and what they talk about, pre-launch scenarios.
Here's a sales force with 800 representatives. Guess what? I would probably be willing to bet you those are the companies whose products fall within this category.
Now, I don't know if I'm making sense or not --
Q. In other words, if they have 800 reps, more likely that they're going to be above the 5 percent --
A. That's what the report is saying.
Q. Right.
So the more you spend -- and -- I

mean, I don't think we're disagreeing, Mr. Simon.
We began the deposition; and you told me that the single, most important thing that has to do with the success of a product is the detailing, the sales forces behind it.
A. The salespeople, exactly.
Q. And this document is consistent with that, isn't it?
A. Well, with -- with that statement, I agree.
What I can't agree with is: I haven't read through this whole document. I don't know what all of it says.
But on the face of it, I can't buy that you need a 20 percent share of voice, so to speak, in order to have this kind of a marketshare.
Q. Can you name for me one product, that didn't have a 20 percent share of voice, that got a 5 percent marketshare -- one branded product?
A. I just haven't thought about it.
I will get back to you.
Q. Okay.

A. I'll think of some.
Q. Please do.
A. Can I keep this?
Q. Yeah.
MR. PARKER: Well, that's the record. So...
MR. DOBIE: Well, that's the record. But we'll get you --
MR. PARKER: We'll make you a copy somehow.
MR. DOBIE: Is that an extra?
There you go.
MR. LOBB: That's the one that you gave me.
THE WITNESS: Thank you very much.
Q. The next part of your report, "B," you talk about Cenestin's marketing message was appropriate for each intended audience; and you mention how appropriate market research was done to position Cenestin.
"Duramed aimed the 'plant based' message to consumers in initial direct-to-consumer

pieces, and this message was presented to physicians to prepare them for consumer requests."
Yeah, this is page 12 of the report, under "B."
You didn't mention -- and maybe you weren't given the information related to it -- that Duramed stopped the direct-to-consumer advertising promotion much sooner than they had planned.
How does that factor into your opinions at all?
A. I knew they stopped. I didn't know that they had stopped earlier than planned.
Q. Okay.
A. How does that plan?
Q. No. I assume that that didn't factor into your analysis.
A. (Witness shakes head.)
Q. All right. You have to respond verbally.
A. No.
Q. Isn't it true that, with a consumer-driven message, direct to consumer is imperative?
A. I don't think it's imperative. I think

it's a -- it's nice to have.
I think that the sales force calling on doctors is where it starts.
And you can do direct-to-consumer in the doctor's waiting room. You don't have to do it in "Ladies Home Journal" or, you know, other publications like that.
Q. The message that Duramed went with, this plant-based message, that is a direct-to-consumer-type message; you would agree?
A. Yes.
Q. And that message --
A. But I don't think that it was totally irrelevant to physicians either.
While physicians didn't make a big deal out of it, while they didn't feel that it was an important message for them, it's still the kind of thing that was perceived and remembered by physicians in the market research.
Q. You're aware of the market research that indicated that only a very, very small portion of physicians cared at all about the plant-based

message; right?
A. Well, it depends on what you call "cared at all" -- or what they called.
And I wasn't there for the research.
So, yes, I don't know what the answer to that question is.
But in terms of them having that information, it was probably something that should have been given to them.
MR. DOBIE: Have you got to change the tape?
VIDEOGRAPHER: Um-hum.
MR. DOBIE: Let's go ahead.
VIDEOGRAPHER: The time is 1:55. This is the end of Tape No. 2.
We're off the record and moving on to Tape No. 3.
(A recess was taken.)
VIDEOGRAPHER: The time is 1:57.
We're back on the record. Beginning of Tape No. 3.
MR. DOBIE: All right. Let me hand

you what was previously marked as Exhibit 619.
And I assume that this is, maybe, the document that you're referencing.
For the record, Exhibit 619 is the "Oral Estrogen Market Overview, Cenestin Launch Meeting" document.
BY MR. DOBIE:
Q. Have you seen this document before, sir?
A. I believe I have.
Q. Okay.
A. I don't recognize "Jeff Kern" as being on the front page.
Q. Mr. Kern was the Cenestin brand manager.
You didn't read his deposition, I take it?
A. No.
Q. Look at page -- it's not Bates numbered. It's in maybe 10 or 12 pages. It says at the top "Cenestin Qualitative Research."
A. Okay.
Q. "Physician reported patient requests."
A. Got it.

Q. And it says that just 6 percent of patients object to Premarin source, and 7 percent of patients request a plant-derived product.
Do you see that?
A. Correct.
Q. All right.
A. Yes, I do.
Q. In light of the fact that physicians are only reporting patient requests for plant-derived product 7 percent of the time, and only 6 percent objecting to Premarin source -- don't you think that a marketing campaign that was aimed at telling patients -- or emphasizing -- is the primary message that Cenestin was a plant-derived product and that Premarin was a horse-derived product was a -- maybe not as good of a message as what they later came up with?
A. The answer to your question is yes, if that's the only thing that they're doing.
My look at the sales aids showed that they were doing more than just talking about plant-derived. They were also talking about the

dissolution, the things that showed superiority of this product over Premarin.
Q. Are you aware of the fact that Cenestin is not 100 percent plant-based?
A. I am aware of that now.
Q. Do you know whether or not Cenestin was ever 100 percent plant-based?
A. I don't have a clue as to what -- what, when, where -- I don't know anything about those.
Q. Now --
A. And everything that I've read, by the way, from the company has been that it is.
Q. That's what they contend -- right? -- throughout all the company documents, is that it's 100 percent plant-based?
A. Well, they don't contend it. I mean, that's the way it reads.
Q. Well, you're not looking at manufacturing documents or raw-material-source things -- you haven't seen anything like that, have you?
A. No, I haven't.
Q. The documents you've seen are the

marketing documents; right?
A. Yes.
Q. All right.
Now, you criticize Dr. Kolassa in his statement that the change in message negatively affects sales because physicians and sales reps, you say, get bored and they want a change.
A. Yes.
Q. All right. Here's what I'm getting at:
Would you agree with me that, when Solvay changed the promotional message, that that was an improvement over the prior message?
A. Yes.
Q. And would you agree that it wasn't just simply a new advertising campaign, it was really a shift in the primary focus -- the primary message that you're going to be promoting?
A. Yes.
Q. All right. And you say that Dr. Kolassa's cardinal rule in marketing, that you never get a second chance to make a first impression, has little relevance in pharmaceutical marketing.

What is the basis for that statement?
A. And in fact, I think I quote one of the exhibits that he used --
Q. Um-hum.
A. -- where -- and my experience, by the way, in the field sales force -- that nobody walks into a doctor's office and makes a sale on his first call.
If there were a product or a sales rep that could do that, he could write his own ticket. I mean, this would be something that everybody would want to buy.
The marketplace and doctors' behaviors -- you know, they're used to writing a particular thing for patients -- requires time and the development of a relationship.
It requires multiple calls.
Q. Have you seen data about how many calls, on average, is needed in order to generate a prescription?
A. I have; but the data is dated.
And it's somewhere along the neighborhood of -- like, on the average of five

calls are required in order to make this.
But, here again, you're talking averages. And you can't -- you can't use averages in this business when you're looking at changing a behavior.
Some doctors are hard. Some doctors are easy. Some doctors don't see representatives. Some doctors, excuse the impression, could be married to a relative of a representative.
So there's a lot of things that go into this.
Q. But having more sales calls -- strike that. We've covered this.
Do you think you can blow a product launch, that you can do such a bad job that it can at least impact the uptake of your product?
A. Can you blow a product launch?
Q. In other words --
A. Yes, you can blow a product launch.
Q. I mean, here's the thing:
When a pharmaceutical product gets FDA approval, there's a certain amount of benefits

you get just from that approval.
And if you only -- you'd agree with that; right?
A. You can't sell it until you get approved, period.
Q. Right.
And it's published in the pink sheets. And, you know, the information is out there. And --
A. Correct.
Q. And if it's -- if you launch a product and the launch is not -- let's just say, hypothetically, if the launch is conducted by people who are inexperienced, who go into a doctor's office and aren't able to talk about the products and compare them in a concise and cogent manner, and your message that is out there promoting the new product is a message that's not appealing to physicians -- that's something that can impact the sales of the product, generally; right?
Would you agree with that?
A. You're saying -- let me see if I can

repeat this.

Hypothetically --

Q. Hypothetically.

A. -- if the message is bad and the representative doesn't know what the representative is doing --

Q. Right.

A. -- and goes into the doctor's office and blows it, the presentation -- doesn't know what he's talking about -- can that have an impact?

Q. Yes.

A. Yes.

Q. And in fact, could it have a significant impact to the success of the product?

A. You mean, a year later or during the first three months or until another representative comes?

Q. Until they get it straightened out. Until the reps are able to speak in a concise and cogent manner, in terms of the attributes of the product versus the competitors'.

MR. PARKER: Objection.

Q. And the message is one that isn't

appealing to the intended audience.

Can that have an impact, a significant impact, over a time period?

MR. PARKER: Objection.

You've changed the hypothetical.

A. Can I --

Q. You could answer.

A. Say it again, because I'm getting confused.

Q. Let's say, even nine months out -- if you still have a sales force that is not able to deliver a concise, cogent explanation of a pharmaceutical product's attributes, and the message to the intended audience is not an applicable message -- can that significantly impact the uptake of the product in the marketplace?

MR. PARKER: Objection.

A. And I'm having a problem, now, with the word "optimal."

Let me state it again.

If you have a bad message that's totally irrelevant, given by a salesperson who is --

doesn't understand sales or the product -- if your question is, for that series of assumptions, could it have a negative impact on the sales of the product? Yes; to the extent that, someone later comes in and gives the right message, it obviously is -- we're talking a whole different ball game.

All right. So if you're talking about -- the first time -- could it impact his ability to make that sale, Day 1? Absolutely. But nobody makes a sale on the first day anyway.

If you're saying that the person never learned through the next -- whatever -- five details on the doctor, then perhaps that could be a problem as well; and hopefully, you would be looking for a new representative in that case.

If you're talking about an individual who can't do it, and then next month -- you know, there's just so many "what-ifs" in this scenario, that it's really hard to assess.

If you've got a good message a month, two, three months later, it might be exactly what the doctor is looking for.

"Oh, why didn't I think of that?"

Or if you're making a message that says: Maybe the reason you're getting breakthrough on your patients at night is because of the bad absorption or the bad pharmacokinetic profile, which is resolved with this -- blah, blah, blah.

And now the doctor goes, "Now I understand why I should use it."

If that's what you're talking about, it's a short-lived phenomenon. The doctor is going to learn about that product over time.

Do I make sense?

Q. No; I think you do. I think you clearly do.

And -- so I understand what you're saying. I just -- here's just sort of a related question:

What you're positing is a situation where, let's say, nine months, a year out -- or whatever -- the sales rep goes and it does it the right way and the doctors get it. Okay?

What I'm wondering is:

Even if they've done everything right in this time period -- the nine months out or year out or whatever -- in your experience, will the product still do a little bit worse than it would have if at the time that the FDA approved the product they had done it right, right from the bat, from the get-go?

THE WITNESS: Are you going to object again?

MR. PARKER: Um-hum.

A. Let me answer this question:

It shouldn't have any detrimental effect, other than to perhaps slow down the point at which you get that doctor's buy-in. So it could have an effect early on.

But I think what would have more detrimental effect is -- and maybe this is the salesman in me coming out -- but if the patient went to the drugstore and couldn't get it because it wasn't on his formulary, who cares? -- no matter how good the sales rep was.

Q. Oh, on the size of the sales force, page

13 of your report --

A. Correct.

Q. -- you say that after adding Cardinal and Solvay sales forces together, Cenestin was detailed by over 300 sales reps. This places Cenestin in the middle of the pack, in terms of sales force size according to Dr. Kolassa's chart.

A. Right.

Q. Isn't it true that what Cenestin ended up getting was about middle-of-the-pack sales?

In other words, it had a middle-of-the-pack sales force. It had a brand-new product.

As you said before, you've got to do a certain number of detailing to reach any physician.

I mean, wouldn't you expect that the results would be sort of middle-of-the-pack --

A. I think --

Q. -- sales?

A. -- if we were just looking at sales force size, I might be inclined to go along with that.

But we weren't.

Q. What else were you looking at?

A. And it really gets into detailing.

When you have a sales force, let's say, like -- pick a sales force -- any company.

We talked about Celexa earlier.

When you've got a sales force from Forrest that's out there selling four or five different products, even though Celexa is their number one product they have to do a heck of a lot more selling of other products and take up more time in the doctor's office to sell those products than was required for the Cenestin sales force.

The sales force, in this particular instance, had one product to detail. So every doctor that they saw got a Cenestin detail.

Sales force size is important; but if they never get direction -- we had what's called "POA" and "non-POA" products at Roche.

"POA" products are those products that are presented to physicians, and they're broken into POAs. So that maybe of the five products that

we're selling, only three were going to be on the campaign for this quarter.

In this case, every time they made a call to a doctor they got a Cenestin detail.

So you got to look more at details than at sales force size.

Q. So it's the number of details that matter?

A. I perceive that it's not only just the number of details, but it's the quality of the detail, the position at which you give the detail to the physician -- at least those things.

Q. So whether or not you detail a physician a first or a second position, that could make a difference?

A. It could make a big difference.

Q. And if the Solvay reps were promoting Cenestin in a second position, for example, behind Estratest or prometrium, that could adversely affect Cenestin?

A. It wouldn't adversely, but it wouldn't affect it positively as well as if it was in a first position.

Q. And you're aware, are you not, that even the Cardinal reps were not just promoting Cenestin; they were also selling Estratest and prometrium?
Were you aware of that?
A. Well, if you look at the audience it doesn't say that they were actually presenting any of those other products. So whether they were or not, I don't know.
Q. But if --
A. I was aware that they were supposed to be looking at those other products. But frankly, I do not know when that was -- when they were responsible to start to sell those.
Q. And you would agree with me that to the extent -- I mean, just based on what you said a moment ago -- that to the extent that the Cardinal or Solvay sales reps were in there promoting all three products, that's not as good as if they were just promoting Cenestin; right?
A. No.
What I'm saying is that if your presentation for Cenestin is done while you're

walking out the door -- what we used to call a "Columbo" when you sell -- if -- "Oh, Doc, did I mention Cenestin? Would you like some samples -- if that is the extent of your detail, that's not as effective as you sitting down, actually having a presentation with the physician, where you're going through features and benefits of the product.
Do I make sense?
Q. Let me ask you about your statements about the effectiveness.
You have prepared a chart in which you --
A. On page 14, now?
Q. Yes.
-- in which you go through IMS data on quality.
A. Yes.
Q. And it's your conclusion that the Duramed sales reps and the Solvay sales reps that were promoting Cenestin were rated in the IMS data as better sales calls than the Wyeth or -- I'm sorry, Wyeth or -- I guess they're Ayerst sales reps --

right?
A. We have a concept that's used in marketing research called "top box scores." That means you look at those that are at the top of the scale. You monitor those over time to look for changes.
In these particular audits -- and it's unfortunate that I couldn't provide the Scott Levin data, because they had actual positions where the details were given in first, second, and third position -- but in these audits, what it shows is that the presentations given for Premarin and rated "excellent" was at 11.4 percent versus Cenestin presentations that achieved an excellence quality rating of 12.9.
Q. Now, do you think that that might be because the doctors have heard about Premarin for the last forty-something years and that Cenestin was a new product, and therefore they're learning something new?
A. I can't tell you why -- I couldn't tell you if perhaps the Premarins were Columbos on the way out from this.

All I can say is that the doctors, at least over the year that this audit compiles data, have rated the Cenestin presentations of a better quality.
Q. On a percentage basis?
A. On a percentage basis.
MR. PARKER: I need a break before too long.
MR. DOBIE: We can break now. That's fine.
VIDEOGRAPHER: The time is 2:17. We're off the record.
(A recess was taken.)
VIDEOGRAPHER: The time is 2:23. We're back on the record.
BY MR. DOBIE:
Q. I was asking some questions about pages 13 and 14 of your report, in Exhibit A, having to do with the effectiveness of the Cenestin sales calls by Cardinal and Solvay.
You reference on page 14 that in July of 2001 12.9 percent of the calls for Cenestin were

rated "excellent," while only 11.4 percent of the calls on Premarin were rated "excellent."

So the difference is 1.5 percent or so?

A. Correct.

Q. Is that, in your view, a difference that's significant at all?

A. I honestly don't know. I don't know.

I've not been working with this audit recently, so I don't know about the statistical value of it.

I think that what would be important would be to trend this over time and look at it, which obviously I did not have the time to do.

But you should note that this is a year's worth of information that's included here, not just the month of July -- which gives it a little bit more relevance.

And they're looking at, also, 200 and -- what? -- 90 -- 270-something details or presentations just for Premarin alone?

That's a pretty significant number.

252 or something like that.

281,000.

Q. Now, you don't really give an opinion about the training of Duramed's sales reps. You say that a longer training period is unnecessary when the sales force is promoting only one product.

Do you know what the average training period is for the promotion of a single product?

A. I know when I was -- when I was brought in and trained at Hoffmann-LaRoche, I went through -- and I'm going to guess I had responsibility for seven products, maybe it was six -- my entire training was four weeks: Two weeks right when I was hired; and then another two weeks about a month, two months, later.

Q. That was in 1976 or so?

A. Yes.

Q. Do you know how that training compares to the training that is done nowadays by --

A. I can't say.

Q. Does --

A. I can say, though -- and I think I

mentioned it in my report -- that these sales reps were all -- they all had a year's worth of experience in order to be hired.

Q. A year's worth of experience, selling?

A. Of selling.

Q. So it could have been they were selling car parts or nails or who knows what?

A. Well, I would assume it wasn't selling car parts. It was at least some kind of selling to people. Not retail selling -- but, yes, you're right.

Q. I'm right, we don't know what kind of --

A. I don't know.

Q. And in your report, you seem to be suggesting that these folks were only promoting one product.

You don't know whether or not they were also promoting Solvay's line of women's products as well?

A. I know that the data, when I looked at the presentations being given for products, it only showed that they were presenting Cenestin.

So if there were other products that they were presenting during the time period I looked at, it did not show up.

Q. The data that you're referencing is what?

A. Is end of year 2000, Scott Levin. That data I looked at. And it did not show them selling anything else.

It's not in this document.

They wouldn't sell me the data.

Q. Have you seen any of the documents that indicate that Duramed, including its president, was concerned that, in fact, Cenestin was not being promoted in the first tier position, at least in 1999?

A. I don't know what the year was.

I saw a document that there was going to be a discussion with David Dod and Mr. Arington, but I cannot remember the date.

And I don't remember the specific memo, whether it was that they weren't doing -- or that he was looking for more.

I knew there was a discussion going

to take place.

Q. Do you think that if the sales reps were more experienced, that that could -- strike that.

As a general matter -- all right? -- without getting into whether they were trained right or weren't trained right -- would you agree that, generally speaking, having sales reps properly trained can impact the success of the sales calls with the physicians?

A. I think that having sales reps trained appropriately is important, if that's what you're asking me.

Q. "Important," in terms of generating prescriptions?

A. Yes.

Q. And let's talk about samples.

You talk about the use of the 30-day sample versus the seven-day sample.

Let me ask you generally first: What is the purpose of samples, from a pharmaceutical marketing standpoint?

A. Well, I do get into that in my report; and

I certainly did not present an exhaustive list.

The purpose of providing samples to a physician is, one, so that he -- and most importantly -- will think about your product when he walks to the closet -- to the sample closet -- and maybe pull your drug down and give to it a patient, and for the physician and the patient to gain experience.

Now, as I also mentioned there's a different value over time to samples.

Samples, when you're -- when you're going out and wanting to gain a physician's experience, may not have the same motivations that you would have in a sample for a product that you had around for years and years, and may or may not have competition to.

For example, Premarin could have -- and I would not suggest that they don't offer samples -- but they wouldn't be impacted to the same extent as Cenestin bringing a new product to market.

If there was a law that said that no more samples will be given to physicians by drug

companies, those products that have samples in the past or have physicians' behaviors already entrenched -- will be a lot more difficult to change those trends without having samples.

Do I --

Q. Let me ask you a follow-up question on that.

The samples -- how are they used by the sales reps when they're detailing the physicians?

A. How are they used? That depends.

It frankly depends on the sales rep, as much as anything.

For the intended use, a sales rep would use them perhaps during his presentation -- to put them out and make it a focal point while he's talking about it with the doctor.

He might try and say, "Doctor, is this enough to start your next ten patients on Premarin or Cenestin?" or something like that? "Do you need more?"

I mean, they can use them as a sales

tool.

They can use them, as I said in the report, as a shelf kind of thing -- just so that they're in front of the shelf, in front of the doctor's mind.

But the most appropriate use that a doctor and a pharmaceutical company would like to see for these products is to gain experience early in a product's life cycle, gain experience with the product. Get the patient to go out and try the drug, see if it works.

Q. In your experience, are samples used by reps -- are they expected to be distributed to the doctors when they make the sales call?

A. Usually, yes.

What you will find is: There are sales reps that may want to use them for other purposes.

And I'm not speaking illegal diversion or things like that.

But let's say you've got a company like Wyeth -- and, please, this is not meant as a

negative -- but a product, as you mentioned earlier, that -- do you think maybe the doctor is tired of the message?

So the representative will go in there and just say, "Hey, Doc, do you need more samples?" And then on his call report to the company -- "Yep, I sold Premarin to this doctor, had a detail for Premarin with this doctor."

So when you asked me, how are they used by salespeople? -- it's a really difficult question to answer, because they could have a lot of different ways that they're using these things.

Q. Is it your experience that physicians view samples, to some extent, as part of the ticket to entry?

In other words, they expect you to bring samples if you're going to be detailing a product so that they can, in fact, try the product out with their patients?

A. Certainly for a new product, yes.

Q. And do you think that if the samples, instead of being brought, are instead mailed in

bulk -- you know, months later, for example -- that that could impact the success of the sales calls with the physicians?

A. It could.

Q. The sampling that you talk about here, you talk about how in your view it was appropriate to use a 30-day-sample pack rather than a seven-day-sample pack.

A. For this particular product in this particular point in time, yes.

Q. And why do you believe that?

A. For a couple of reasons.

This particular market -- let me drop back a foot.

My son works for Parke-Davis. My son launched FemHRT.

He works for Pfizer now. He no longer sells FemHRT because the primary-care-physician audience is no longer one of their targets.

This is something Wyeth does not know -- yet.

They have a specialty sales force, of which my son used to belong; and he, as well as another sales rep in that company, have told me that multiple samples are typically given to people, not seven-day -- even though they have a seven-day sample pack -- their product is packaged that way -- but that that's not the way the doctors use it.

And by the way, the documents that I reference in here from Wyeth even mention that they wanted to go to a 30-day sample.

Typically, in this marketplace a doctor wants the patient to have enough experience on the drug; and it doesn't work in seven days.

So for a new patient coming in, you want to gain that experience, and make sure that you've got the right product and the right dosage and everything else.

And that's why I say, for Wyeth -- it's not as important, for a company like Wyeth, where your doctor is probably giving the sample out for patients that only need to get over a couple of days while they're waiting to get to the pharmacy or

waiting for their mail-order prescription to come -- seven days is sufficient.

Q. You said a lot of things there. So I want to make sure that we cover them.

A. I hope not too much.

Q. You said that Wyeth wanted to go with a 30-day sample.

There's one person in one document that you're referencing that suggests a 30-day sample; right?

A. That is correct.

Q. And do you know whether or not --

A. I don't know that it was one person or -- it looked to me like a presentation.

Q. Do you know what happened to that presentation or what was done with that suggestion?

A. Certainly not.

Q. Do you know whether or not Wyeth ever went with a 30-day sample for Premarin?

A. I don't think it makes sense for Wyeth to do it.

Q. Do you think it makes sense for Duramed to

have -- do you think it would have made sense for Duramed -- strike that.

First, you don't know whether or not Wyeth ever went with a 30-day sample?

A. Absolutely, I do not.

Q. And do you know whether, in fact, Duramed went with a seven-day sample once they were able to do it?

A. I don't know that.

Q. And do you think that if they were projecting selling 600,000 30-day packs in 1999, and instead they gave away that same number -- that that could have impacted what their sales were in the first year?

A. I think that those are two disjointed things we're talking about: 600 samples -- 600,000 sample packs versus 600,000 bottles that they hoped to sell.

If they got physicians to use those samples as samples, then they would have sold a lot more than 6 percent.

Do I make sense?

Q. Well, I'm not sure.

If they had projected in the course of a whole year that they were hoping to sell 600,000 bottles of Cenestin, and instead they gave 600,000 away for free -- 30-day samples -- don't you think that might have impacted what their sales were?

A. I would think that possibly they were thinking: If I gave away 600,000, maybe I'll get 50 percent marketshare.

Q. So here's the point:

It might have come back in subsequent years to their benefit; but it certainly could have impacted what the sales were in the first year.

Right?

A. I'm missing the point.

To me a sample is a starter pack. It's used to get a patient started and acclimated on a product.

It's not used to fill the channel, and they aren't getting to the shelf.

If they are getting to the

prescription shelf in the pharmacy, then there is something illegal going on. That shouldn't be where they're at.

It's meant to motivate a prescription from a physician.

Q. You mentioned FemHRT, and you mentioned your son's experience with seven-day versus 30-day samples.

Do you know what percentage of the FemHRT samples are seven days versus 30 days?

A. I have not -- I do not know.

I would guess that a large percentage of them were seven-day.

Q. The other products that are in the ERT category -- do you know whether or not they, as a rule of thumb, use seven-day samples?

A. No, I do not.

Q. Do you know whether they use 30-day samples?

A. No, I do not.

Q. Do you know whether there is anybody in the ERT marketplace that uses anything other than

seven-day samples, with the exception of Duramed's 30-day sample?

A. I do not.

Q. If the president of Duramed testified that he believed that the use of 30-day samples would have slowed the uptake in prescriptions of the product, do you just disagree with that?

A. Say that again.

Q. If the president of Duramed testified that he believed that the use of 30-day samples slowed the uptake of prescriptions, you'd just disagree with that?

A. No, I don't.

Q. If the director of marketing for Duramed stated the same thing, would you disagree with that?

A. No.

Q. The discussion that you have here about the relative cost of a 30-day versus a seven-day sample -- would you explain that for us, please?

A. The active-ingredient cost for most prescriptions -- most prescription products -- will fall somewhere between 3- and $4.

And that's not just active ingredients. That's what it costs to actually -- from raw material, purchasing of raw material, to the actual production of a bottle of 100 tablets.

The packaging costs are typically looked at as about $1.

And that's for components. That's for the bottle, the cap, the safety cap, the label, the package insert.

And some people package them in boxes. It could be a little bit more expensive.

That's going to be about $1.

Now, when you blister-pack it's even more expensive -- because you've got to go through a process of not only packaging this, but you've got to worry about --

Your materials are an independent process. It's a smaller-batch kind of process.

But the bottom line is: It's about $1. Whether you're packaging 100 or you're packaging seven, it's going to be about $1.

So if -- my point is: If you are

going to take 30 tablets, let's say, and break them into packages of seven, you're looking at somewhere in the neighborhood of 90 cents' worth of ingredients' cost in that 30, and $1 for the package.

So you're talking about $1.90, something along those lines, for a bottle of 100 -- versus -- if you're talking the three different packages -- you're talking for that same 30, $3 just in packaging costs.

Actually -- I take that back -- $4.

Twenty-eight tablets would be four packages; correct?

Q. You mentioned "FemHRT" a moment ago.

Do you think that that's a good benchmark for what Cenestin should have done in the marketplace?

A. I honestly don't know. I haven't looked at it. I have not attempted to.

Q. Do you know how many sales reps Pfizer had promoting FemHRT?

A. Do I know how many Pfizer had?

Q. Uh-huh.

A. No.

Q. Do you know, in total, how many sales reps were engaged to promote FemHRT?

A. I do not.

I know how many were at Parke-Davis was -- I take that back. I'm not 100 percent certain I know about Parke-Davis.

Q. What is your best estimate of how many were at Parke-Davis?

A. Well, I was told the Women's Healthcare Group was only 150 people.

Q. And the product was jointly promoted with Pfizer, though; right?

A. Not when they launched it.

Q. When did they begin jointly promoting it?

A. When Pfizer bought them.

Q. When was that?

A. Pfizer bought Warner-Lambert -- what? -- two years ago.

Q. So some point in 2000?

A. I'm really guessing.

Sometime between '99 and 2000.

Q. Page 17, you say: "While I agree that it's the standard practice in the pharmaceutical industry for drug manufacturers to enter into rebate contracts, several aspects of Wyeth's contracts take them outside of the norm."

Okay. Now, first, in terms of what the "norm" is on branded pharmaceutical companies' rebate contracts -- the experience that you identified for us this morning was the experience that you had at Hoffmann-LaRoche; right?

A. Bristol-Myers, not --

Q. And Bristol-Myers?

A. And -- as well as my experience at Teva.

That's it.

Q. And the rebate contracts that you're referencing at Teva -- we talked about that this morning -- that related to a generic product; right?

A. Yes.

Q. And at Bristol-Myers, I think you told me you weren't aware of what the rebate contracts were on the Estrace products; right?

A. Correct.
Q. And what rebate contracts are you familiar with at Bristol-Myers, if any?
A. I wouldn't be aware of any of them now. The only -- none.
Q. All right. And at Hoffmann-LaRoche, what rebate contracts are you familiar with?
A. None.
Q. So when you say that the contracts are outside the norm, what's the basis for that statement?
A. My industry experience and going to -- having discussions with these individuals.
I have talked -- whether it was with brands or generics, I still talk with the individuals; have friends at PCS, as a matter of fact.
So, it's discussions with them.
Q. But in fairness -- I mean, do you think -- these contracts are not publicly-available contracts, are they, generally?
A. No.

Q. And in fairness, do you really think you have an understanding of the ins-and-outs of these contracts, such that you can give expert testimony, under oath, as to what the "norm" is for rebate contracts from 1991 to the present?
A. I would not hold myself out to that. You're correct.
Q. All right. Now, you state in that paragraph 17, under "First," that the bundling is more accepted in the generic industry because generic products are available from multiple sources and are interchangeable.
What is the source for that?
A. My experience and discussions with people at PBMs.
Q. So, generics -- they do bundle those?
A. Generics are bundled; but you don't -- you don't sell generics, principally, to PBMs.
Q. I see. So they would be bundled at GPOs and --
A. Exactly.
Q. I understand.

Now, the exclusivity -- you say: "It's not a standard practice in the industry for a drug manufacturer to have exclusive contracts with virtually every major PBM and MCO."
Is it your belief that Wyeth had exclusive contracts with virtually every major PBM and MCO?
A. It's my belief that Wyeth had contracts that required exclusivity, whether they were called "sole source" or were contracts that had rebates assigned to them, such that they would lose their funding, yes.
Q. So between contracts that talk about sole source of conjugated estrogen and rebate contracts -- those together, those are where you're saying that Wyeth had them with virtually every major PBM and MCO?
A. With the major, yes.
Q. Now, I assume that you read in Dr. Kolassa's report where he had examples of different products, where there was exclusive contracts, rebates.

You mentioned before your work with AstraZeneca. We talked about the PPI category briefly.
But you'd agree with me that there are other situations in the marketplace where folks have rebate contracts and exclusivity in the PPI category, with Cox-2 inhibitors, with insulin, with growth hormones, with certain urinary -- I got to think of the name of the product --
A. "Ditropan"?
Q. -- that those were all situations where you may have exclusives and rebate contracts?
A. I agree that all of those can have rebate contracts or might have rebate contracts; but I can't say that I've looked at all of those to find out if they do or they do not have exclusives.
Q. Oh, the next paragraph, "Third" -- you say: "It is not standard practice for a drug manufacturer to refuse to renegotiate a contract if an MCO or PBM wants to add another formulary agent, as was the case with Wyeth's refusal to renegotiate with Express Scripts."

And let me ask you about that.
You mentioned the Sally Miller e-mail -- that you're familiar with that, on Express Scripts.
Are you aware of any information that suggests that Express Scripts asked to renegotiate its contract with Wyeth?
A. I read somewhere that they had mentioned to Wyeth that they had gotten -- and I don't think it was in Sally Miller's memo -- but that they had gotten requests from a rather -- how do I want to put this? -- vocal group of physicians, requesting that Cenestin be added to the formulary -- something along those lines.
Q. Right.
A. And that they wanted to renegotiate the contract.
Q. You think that was for Express Scripts?
A. I think that was for -- I could be wrong.
I think that was for Express Scripts, yes.
Q. I think I asked you this already:

You weren't aware of the fact, when you prepared this report, that, in fact, Express Scripts then added Cenestin to formulary?
A. Well, I was aware that they added it, but then took it off.
Q. Right. And then they added it back on; you were not aware of it?
A. I was not aware that they added it back on.
You're saying it's on now?
Q. (Counsel nods head.)
A. When did they add it back on?
Q. The following year.
A. So, this year?
Q. No; in 2000 -- fall of 2000.
Prescription Solutions, are you aware of whether or not there was any request on the part of Prescription Solutions to renegotiate?
A. I read a memo that went to Taka Tomo along those lines.
I think I'm -- I think that's the right individual.

Q. You say that -- "It is quite apparent that physician requests to have Cenestin added to the formulary were unavailing for even these large market participants."
What are you relying upon here?
A. Those documents -- like, Sally Miller document -- even though the doctors asked for it, they weren't going to get it.
Q. So that's Express Scripts and Prescription Solutions.
Is there anything else?
A. Oh, no.
Q. The next heading that you've got here is on "Wyeth Preemptive Plan."
A. Correct.
Q. Just as we talked about this morning with Sigma-Tau, your other company -- you don't in any way dispute the idea that even a market leader, just like your company, has the right to vigorously defend its market?
A. "To vigorously defend its market"? Absolutely not.

Q. And it's standard practice to anticipate and respond to competition?
A. Yes.
Q. And forecasts regarding the impact of a new entrant in the marketplace, those are typical? You, in fact, do those type of forecasts?
A. Yes.
Q. And is it a standard practice to develop an action plan to respond to a new entrant?
A. Yes. I would say yes.
Q. And would that include education of the sales force and developing sales materials?
A. It would.
Q. At the top of page 19, you say: "Wyeth was not competing on price."
And then you talk about how Duramed documents show that the rebated prices for Cenestin were in some instances far below rebated prices for Premarin.
Were you shown the documents that showed just the opposite -- that in many instances, Wyeth's Premarin prices were below Cenestin's?

A. No.
And by the way, they weren't referenced in Kolassa's document. Even Kolossa's document showed that prices were lower -- or rebates, if you will, were larger -- for the Cenestin product than for Wyeth's product.
Q. Have you reviewed Dr. James's report that looks at all of the publicly available --
A. I don't know Dr. James.
Q. -- the available data regarding price?
A. No.
Q. Can you give me an example where Cenestin's rebated price was lower than Premarin's?
A. I believe I made reference to a couple of them in here.
I want to say Express Scripts was one of them, I think.
I'm not sure about Prescription Solutions. I don't remember the actual...
Yeah, Prescription Solutions.
Q. Now, you talk in the next sentence about, in the case of Aetna, Wyeth shared part of the

preemptive plan with -- I guess -- with Aetna and the Cenestin impact model to demonstrate to Aetna the rebates on all Wyeth products that would be lost if the marketshare was moved to Cenestin.
A. And that should be all products that were on their formulary.
Obviously, not all Wyeth-Ayerst products.
Q. Let me ask you about that.
The other products that Aetna had on formulary were things like oral contraceptives; right?
A. Some of it.
I don't remember the specific products for each company; but they would include things like their Effexors, their NSAID products, they're antidepressant products -- those kinds of things.
Q. And there's a tremendous amount of competition within, let's say, the antidepressant category -- between Effexors and Prozacs --
A. All their product lines are competitive, I

think.
Q. All right. And so if Aetna wanted to cancel their contract with Wyeth and go with Cenestin instead, they could still put an oral contraceptive from Johnson & Johnson on formulary. They could buy antidepressants from Eli Lilly. They could do -- they could cut similar deals as they did with Wyeth; right?
A. Well, that's a two-part question.
Yes, they could cancel the contract; but they're a public company, for the most part. Most of these are public companies.
And the question is: Are you going to be willing to give up -- I mean, in the one instance Sally Miller -- which didn't jive, by the way with the report -- mentioned that I think it was Express Scripts or -- would lose 40 million -- no, it wasn't Express Scripts, it was someone else -- but would lose $40 million in rebates if they put Cenestin on formulary. I mean, that was the implication.
And as a public company, can you

afford to do that kind of thing?
Q. Here's what I'm getting at:
If you're an Express Scripts -- you've got a contract with Johnson & Johnson already anyway, don't you?
A. Correct.
Q. And you've got a contract with Eli Lilly already anyway; right?
A. Correct.
Q. And they'd be more than happy to sell you their oral contraceptives rather that Wyeth's or their antidepressants rather than Wyeth's; right?
A. Correct.
Q. So all you would be doing would be switching from a "Wyeth-rebated" product to "Johnson-&-Johnson-" or "Eli-Lilly-rebated" product?
A. Let me say that that's easier said than done.
I don't know how long it's going to take for you to get those contracts done. Contracting takes time.
I don't know what the prices will be

at which they're going to rebate those products.
I think that, in the case of a lot of these companies, you've worked with a manufacturer to develop promotional campaigns and things to help move products.
It would be not in either person's interest to see that these things just evaporate or that your efforts and costs just -- or rebates -- just go away.
And even if they were the same thing, if we used that example -- although $40 million is inflated -- if we used that example and take that over a couple months' worth of time -- you know, if three months you're talking about $12 million.
You're losing $12 million while you're going -- converting from one to the next.
Now, you're also putting out all these new books and everything, and promotional materials that you've already got in the marketplace.
It's not the kind of thing that is -- you know, you just turn on a dime and, you know, you

"close-this-window-and-open-this-door" kind of thing.
Q. So another company, like a Johnson & Johnson, on oral contraceptives -- or Eli Lilly -- they'd have to be very aggressive if they were going to get that oral contraceptive or antidepressant market away from a Wyeth -- right? -- because of those costs?
A. Well -- now we're talking the difference. Now we're talking about Johnson & Johnson going at them.
Q. Yes.
A. The deal with -- at least as I understood these contracts, was: None of those products were sole source.
The only one that requested sole source was Premarin.
So if a Johnson & Johnson comes in with their conception-control, birth-control pill and they want to make a switch, it's strictly -- here's an up and up -- you know, it's based on price, period.

We're not throwing the rebates for all of these other products into the mix -- which you are, when you're saying Premarin is sole source.
Q. But because of that, would it be -- I mean, if you're correct that there was a sole-source contract with Express Scripts that prevented Cenestin from being placed on formulary -- and let's set aside what happened in the fall of 2000 -- the fact of the matter is: They wouldn't necessarily lose all of those rebate dollars, because they could, number one, sign a rebate contract with Duramed for Cenestin; and they could sign a rebate contract with Eli Lilly or Johnson & Johnson for the Effexors and oral contraceptives; right?
A. This is really theoretical.
Q. Yes.
A. Theoretically, they could do all those things. But theoretically, they could also do them and lose money -- as opposed to what they had going on in the past.
Q. Or theoretically, they could make money -- if Eli Lilly or Johnson & Johnson offered them a

better deal, and Cenestin did as well?
A. Well, they typically are going to be -- yes. The answer to your question is yes.
Q. What you're saying in your report is that none of these managed-care organizations could renegotiate.
Other than the situation with Prescription Solutions and Express Scripts, are you aware of any other managed-care organizations that sought to renegotiate and Wyeth refused?
A. I have not seen -- no.
Q. In your conclusion of your report --
A. But what I did see was the document that was prepared by Wyeth with those contracts in the model and all of the individuals.
And they very clearly are all organized the same way, showing: Here's what you lose -- and they included a lot of organizations -- here's what you lose if you decide to take on Cenestin.
Q. Do you know whether or not those documents were ever used with any managed-care organization,

other than Aetna?
A. I don't.
Q. At the conclusion of your report, you say that Dr. Kolassa views that the deficiencies of Cenestin and the marketing efforts of Duramed and its partners were wholly responsible for the low sales of Cenestin, and you view that that's not correct in your opinion.
A. Correct.
Q. Would you agree that it could be at least partly responsible for some of those low sales?
I don't even want to call it "low sales," but just --
I've showed you today IMS data. We've looked at the government report.
Don't you think that spending less money than what they spent, having this being the very first time that they had ever sold a branded product, a brand-new sales force out there -- that that could at least be partly responsible for what the sales are that they, in fact, achieved?
A. Let me answer that question this way:

I think that if they were to spend more money they could potentially get more sales; but let me also premise that by, they weren't looking to set the world on fire. They were looking for a 6 percent share of this marketplace.
So, I really don't know how to answer your question.
MR. DOBIE: Let's take a break. Let me go through my notes.
VIDEOGRAPHER: The time is 3:09. We're off the record.
(A recess was taken.)
VIDEOGRAPHER: The time is 3:17. We're back on the record.
BY MR. DOBIE:
Q. A few last questions on your background.
We talked about your educational background. What formal training have you had, from an education standpoint, on pharmaceutical marketing?
A. What educational?
Q. Yes.

A. Other than going to courses that are offered in the MBA programs -- you know, like the -- there are market research courses held by the bases group that used to be held. I used to go to those.
I was a member of PMRG.
I did start an Executive MBA program, but left that to accept my position at -- in the home office -- besides the fact that it was taking up too much of my time.
Just mostly -- and -- mostly just classes, things that would be provided for me -- week-long classes on forecasting methodologies -- those kinds of things -- financial planning for non-financial managers.
When I was at Bristol-Myers, we were required to go through two of those training programs a year; and in my case, not only did I go to those but I also went to some of the off-site programs.
I was involved in the recruiting effort for the MBA students and MBA programs at Bristol-Myers. We used to bring in business

interns.
As a matter of fact, a lot of the executives that are in Bristol-Myers today went through the program where I used to actually interview the candidates for bringing into the company.
So those kinds of things, I guess I would say.
Q. But recruiting MBAs isn't --
A. No. Talked about programs as well.
Q. But as an undergraduate -- in your undergraduate education, did you ever have a class in pharmaceutical marketing?
A. No.
And when I went to school, there was no such thing as a class in pharmaceutical marketing.
Q. What marketing classes did you have?
A. Just the ones that I took in my -- in the Executive MBA when I started.
And I did not finish them.
Q. So undergrad, there were no marketing

classes?
A. Nope.
Q. And then in the MBA program, you started some classes but didn't finish them?
A. Correct.
Q. And then the classes that you were describing along the way in your career, were those classes that took place at Bristol-Myers?
A. Well, Bristol, as well as Hoffmann-LaRoche. And --
Q. Bristol, let me start there. Were those in Syracuse?
A. No; those were in Evansville.
Q. Where was the Executive MBA program that you were --
A. Florida Atlantic University.
Q. I met another graduate from there recently.
A. They were one of the first with the Executive MBA program. They're very good.
Q. Hoffmann-LaRoche, where were those classes held?

A. Oh, my gosh. I couldn't tell you.
I mean, we had our own institute for small things; but I can't tell you where I went for classes.
Q. All right. I mean, during the time that you were at Bristol taking classes, and Hoffmann-LaRoche -- I think you told us that you had four weeks of training, when you started at Hoffmann-LaRoche, on sales training.
With all of these classes that you took at Hoffmann-LaRoche, how many weeks of classes would you have had in total?
A. A typical class at Hoffmann-LaRoche would be a week.
For example, if you were taking a targeted selection course -- management training -- or if you were going through an assessment center -- these are typically week-long kinds of events.
Q. You do, like, one a year?
A. Yes; but we'd also do off-campus kinds of things.
Q. At Hoffmann-LaRoche, that training would

involve issues beyond pharmaceutical marketing.
You would be studying, I assume -- like you said -- management issues, generally; financial planning -- things like that. Or would you say you had one class per year on pharmaceutical marketing?
A. No. I think you're right. I think you're -- there would be general.
Q. And how about at Bristol-Myers; the same sort of deal?
A. Pretty much the same -- same kind of thing.
Q. About once a year, and a variety of management courses?
A. Well, yes.
But you've got to understand that you get -- the education that you get by being there -- for example, when I was at Hoffmann-LaRoche, we were looking at -- and we had this downsizing that you referred to earlier -- we wanted to look at: What would be the appropriate sales force size? -- etc.
Those kind of questions would come

into, perhaps, a marketing research.
In my capacity, I participated in that program and designing, actually, how big the sales force should be, along with the general manager of the company --
Q. So that's --
Go ahead.
A. So -- yeah, that's on the job.
But the real education that you're going to get in this industry typically comes from there.
Q. Understood. Understood.
And I don't mean to denigrate that in the least. I'm just trying to understand, in terms of classes -- because I understand the on-the-job, I think.
A. Correct.
Q. So set aside on-the-job training.
In terms of class training at Bristol-Myers, would you say the same sort of thing: About once a year, a variety of different management courses, including pharmaceutical --

A. Twice a year.
Q. Twice a year.
-- pharmaceutical management?
A. Correct.
MR. DOBIE: Understood.
Nothing else.
MR. PARKER: Thank you.
VIDEOGRAPHER: The time is 3:24.
This is the end of today's deposition.
(Whereupon, signature not having been waived, the taking of the deposition concluded at 3:24 p.m.)
* * *

CERTIFICATE OF NOTARY PUBLIC

I, Susan D. Ashe, the officer before whom the foregoing deposition was taken, do hereby certify that the witness whose testimony appears in the foregoing deposition was duly sworn by me; that the testimony of said witness was taken by me in stenotype and thereafter reduced to typewriting under my direction; that said deposition is a true record of the testimony given by said witness; that I am neither counsel for, related to, nor employed by any of the parties to the action in which this deposition was taken; and further, that I am not a relative or employee of any attorney or counsel employed by the parties hereto, nor financially or otherwise interested in the outcome of the action.

Dated: October 17, 2002

_____
Notary Public in and for the District of Columbia

My commission expires:
April 14, 2007

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION AT CINCINNATI

- - - - - - - - - - - - - - - - - - - x
DURAMED PHARMACEUTICALS, INC., :
Plaintiff, :
vs. :
WYETH-AYERST LABORATORIES, INC., :
Defendant. : PAGES 1 - 275
- - - - - - - - - - - - - - - - - - - x

I, Paul Simon, do hereby acknowledge I have read and examined the foregoing pages of testimony, and the same is a true, correct, and complete transcription of the testimony given by me, and any changes and/or corrections, if any, appear on the attached errata sheet signed by me.

_____ _____
Date Paul Simon
SUBSCRIBED AND SWORN TO before me
this _____ day of _____, 2002.

_____
Notary Public

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J

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